United States Senate <u>HEALTH, EDUCATION, LABOR, AND PENSIONS COMMITTEE</u> Patty Murray, Ranking Member

Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients



Minority Staff Report

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Executive Summary

In September 2013, staff at Virginia Mason Hospital and Medical Center in Seattle, Washington, traced a cluster of antibiotic-resistant infections in patients to a medical device called a closed-channel duodenoscope, which is used to identify and treat conditions of the pancreas and bile duct. Around the same time, staff at Advocate Lutheran General Hospital outside of Chicago, with the help of the Centers for Disease Control and Prevention, similarly linked an outbreak of superbug infections to closed-channel duodenoscopes.

- Both hospitals concluded that closed-channel duodenoscopes remained contaminated even after proper cleaning, spreading bacteria between patients, but it took 17 more months for duodenoscope manufacturers and the Food and Drug Administration (FDA) to alert hospitals, doctors, and the public to the risk posed by the devices.
- In January 2015, after several outbreaks of serious infections, including in Seattle, became public, Senator Patty Murray, the Ranking Member of the Senate Health, Education, Labor, and Pensions Committee, initiated an investigation to determine the extent of duodenoscope-linked infections, understand the slow response, and determine if legislative changes were needed to prevent similar problems in the future.
- Senator Murray's staff investigation has demonstrated that the clusters of infections at Virginia Mason and Advocate Lutheran were not isolated incidents. Between 2012 and spring 2015, closed-channel duodenoscopes were linked to at least 25 different incidents of antibiotic-resistant infections that sickened at least 250 patients worldwide.
- The investigation found that by early 2013, Olympus, the manufacturer of 85 percent of the duodenoscopes used in the United States, knew of two independent lab reports finding that the closed-channel model duodenoscope could harbor and spread bacteria even after cleaning according to the manufacturer's instructions. Olympus never brought this information to FDA, and did not alert hospitals, physicians or patients in the U.S. to the risk of infection until February 2015.
- The investigation also found that Olympus, as well as the other two manufacturers of duodenoscopes used in the United States, Pentax and Fujifilm, and Custom Ultrasonics, the manufacturer of the automated cleaning machine in use at many of the hospitals that experienced infections, failed to meet the obligations placed upon them by the current regulatory system. Two of the manufacturers failed to seek FDA clearance before selling the "closed-channel" duodenoscopes, all failed to adequately test whether the scopes could be cleaned reliably in real-world settings, and fully comply with adverse events reporting requirements.
- Additionally, although at least 16 separate U.S. hospitals traced antibiotic-resistant infections directly to duodenoscopes, the hospitals generally did not raise alarms about these infections with federal regulators. It appears that not a single hospital that experienced infection outbreaks tied to the duodenoscopes sent the required adverse event form to the device manufacturers.
- When hospitals did take required action to report adverse events to device manufacturers it was often late, notification was made informally by phone or email, and reports were not

inclusive of all the information necessary for the manufacturers to themselves submit accurate and complete information to FDA.

- While FDA started investigating how closed-channel duodenoscopes cleaned according to manufacturers' instructions spread infection in September of 2013, the agency took no action to alert hospitals, doctors and the public to the risk posed by closed-channel duodenoscopes for 17 months. At least 68 patients in seven different hospitals in the United States were infected with antibiotic-resistant bacteria linked to duodenoscopes during this period.
- Problems with FDA's outmoded adverse event device database, as well as slow and incomplete reporting by manufacturers and hospitals, appear to have left FDA staff unable to develop an accurate sense of the frequency and severity of the infection outbreaks. FDA was also unaware that by early 2013, two independent labs in Europe had documented the Olympus closed channel duodenoscope remaining contaminated after repeated cleaning, or that a Dutch Health Ministry report in 2013 had already concluded that Olympus did not have the data to show their cleaning instructions worked consistently and effectively.
- As a result, the FDA wasted valuable time seeking cleaning data from manufacturers and trying to conclusively determine that cleaning mistakes by hospital staff in cleaning were not the responsible for the infections. Unlike FDA's surveillance of drugs, where the agency is increasingly able to use the "Sentinel" system to develop fast and accurate information about adverse events, FDA had no way to seek independent information about adverse events linked to medical devices.
- The failure of FDA's current device safety reporting system to rapidly identify duodenoscope-related, antibiotic-resistant infections, including superbug infections, should serve as warning that without a comprehensive postmarket device surveillance system that supplements self-reporting from hospitals and manufacturers, future device issues are likely to go undetected for far too long and with life-threatening consequences.
- To minimize future delays in identifying and addressing device safety issues, the report recommends:
 - Congress require unique device identifiers (UDIs) to be included in insurance claims and fully fund a National Medical Device Evaluation System to ensure that FDA is able to effectively monitor the safety of medical devices on the market rather than relying on adverse event reporting.
 - FDA quickly evaluate the design of closed-channel duodenoscopes and implement a phased recall to fix or modify the devices if necessary.
 - FDA update its guidance to clarify when manufacturers are required to seek 510(k) clearance when medical devices are modified, and that Congress clarify FDA's authority to deny a 510(k) application in the absence of sufficient data to demonstrate a medical device can be safely cleaned and reused.
 - FDA implement new draft guidance to more quickly disseminate information to health care providers when the agency becomes aware of information that patient safety might be compromised by a medical device; and
 - Compliance by hospitals with adverse event reporting related to medical devices be made a Condition of Participation in Medicare.

Introduction

In the summer of 2013, staff at Virginia Mason Hospital in Seattle, Washington realized that multiple patients were contracting the same type of antibiotic-resistant infection after undergoing a specific procedure at the hospital. By September 2013, after conducting an extensive epidemiological investigation in conjunction with the King County and Washington State Health Departments, the hospital linked the infections to closed-channel duodenoscopes. Duodenoscopes are medical devices used in a procedure called endoscopic retrograde cholangiopancreatography (ERCP) to diagnose and treat problems in the bile or pancreatic ducts. By the time the hospital successfully contained the outbreak of infections after undergoing ERCP.¹ At least eleven of those patients later died, although it is unclear whether those deaths were a direct result of the infections.²

During the same period in 2013 when patients at Virginia Mason were falling ill, 32 patients contracted carbapenem-resistant Enterobacteriacea (CRE), a bacteria that is resistant to even the most potent antibiotics, after undergoing ERCP at Advocate Lutheran General Hospital in Park Ridge, Illinois. CRE is a deadly bacteria, often called a "superbug," that kills almost half of those infected. The Centers for Disease Control and Prevention (CDC) investigated the outbreak after Advocate Lutheran requested assistance with identifying the source of the bacteria and containing the infection. By September 2013, CDC and Advocate Lutheran had determined that the CRE outbreak in Illinois – like the outbreak in Washington – was linked to ERCP procedures using closed-channel duodenoscopes.

After *The Seattle Times* broke the news in late January 2015 that Virginia Mason had experienced an outbreak of antibiotic-resistant infections in ERCP patients, Senator Patty Murray, Ranking Member of the Senate Committee on Health, Education, Labor, and Pensions (HELP), initiated an investigation into these dangerous duodenoscope-linked infections. In February and March 2015, Senator Murray sent two letters to the Food and Drug Administration (FDA), and in June she sent requests for documents to the three manufacturers of closed-channel duodenoscopes sold in the United States: Olympus Medical Systems (Olympus), Hoya Corporation PENTAX Life Care Division (Pentax), and Fujifilm Medical Systems (Fujifilm). All three manufacturers provided significant information in response to the request, including previously unavailable independent reports provided by Olympus. Senator Murray's staff also conducted interviews with hospitals, subject matter experts, independent investigators, state and local health departments, CDC, and FDA.

Senator Murray's staff investigation has demonstrated that the clusters of infections at Virginia Mason and Advocate Lutheran linked to closed-channel duodenoscopes were not isolated incidents. Between 2012 and spring of 2015, the Olympus closed-channel duodenoscope used at Virginia Mason, together with closed-channel models made by Pentax and Fujifilm, were linked to at least 25 different instances of antibiotic-resistant infections that sickened at least 250

Between 2012 and spring 2015, closed-channel duodenoscopes were linked to at least 25 different instances of antibioticresistant infections that sickened at least 250 patients worldwide.

patients worldwide. Because some of the identified infections had unique markers that made the

bacteria possible to track, and because the hospitals that have reported infections are primarily large research hospitals and medical centers adept at spotting and addressing antibiotic-resistant infections, it is likely that there are more incidents of infections linked to these devices that have never been identified.

The investigation found that Olympus, the manufacturer of 85 percent of the duodenoscopes used in the United States, knew by May 2012 that the closed-channel duodenoscope model used at Virginia Mason could harbor and spread bacteria even after proper cleaning. By the fall of 2012, Olympus was aware that its duodenoscopes had been linked to antibiotic-resistant infections, including superbug infections, caused by life-threatening multidrug-resistant organisms at hospitals in both the United States and Europe. By early 2013, independent laboratory tests of at least two different closed-channel duodenoscopes showed the devices remained contaminated after careful repeated cleaning and reprocessing.

Despite this, Olympus issued no safety alerts or guidance to hospitals and physicians in the United States until February 2015 – almost three years after first realizing the problem in April 2012. In contrast, Olympus sent some hospitals in Europe two separate alerts in 2013 and 2014, which, at the very least, advised extra caution when cleaning these duodenoscopes.

Olympus, Fujifilm, and Pentax also failed to meet their obligations to provide FDA with the

At the time duodenoscope manufacturers sold their devices to hospitals in the United States, they lacked sufficient data to show their cleaning instructions worked. information the agency needs to keep patients safe. Olympus and Fujifilm never applied for FDA clearance for the new design of the closed-channel duodenoscope before selling the devices in the United States. The manufacturers also attested to FDA that they had tested their duodenoscope cleaning instructions and demonstrated that they worked reliably. However, none of the manufacturers actually had sufficient data to show that duodenoscopes could be reliably cleaned between

uses. Finally, the manufacturers did not consistently report the information they had regarding infections linked to the devices.

Additionally, the investigation found that many, although not all, of the domestic hospitals with duodenoscope-linked outbreaks used an automated endoscope reprocessor (AER) manufactured by Custom Ultrasonics. Custom Ultrasonics, like the duodenoscope manufacturers, failed to meet its regulatory obligations, including filing appropriate applications with FDA, testing its machines sufficiently to make sure they worked, and filing complete and accurate adverse event reports. In November 2015, FDA issued a mandatory recall of all Custom Ultrasonics AERs.

Further, the investigation established that although at least 16 separate domestic hospitals traced antibiotic-resistant infections directly to ERCP procedures, as a group, the facilities generally failed to quickly raise alarms with FDA and CDC. In some cases, hospitals completely failed to make the required reports of infections to the devices' manufacturers. This limited and slow reporting by hospitals likely impaired FDA's ability to accurately assess the frequency and severity of outbreaks of duodenoscope-linked infections.

Failures by device manufacturers and hospitals to quickly and completely disclose important information to FDA, and FDA's outmoded adverse event system, hampered the agency's ability to accurately assess and respond to the infections. Because FDA did not have prompt and complete

information, it took the agency overly long to accept that duodenoscope-linked infections were not the result of hospital cleaning errors. As a result. contaminated duodenoscopes spread serious infections for at least three years before manufacturers and FDA alerted hospitals in the United States. FDA's first safety communication regarding duodenoscope cleaning did not occur for almost 17 months after the agency first became aware of the spread of infections. In the interim, at least 68 patients were affected in seven different hospitals in the United States.

Between the time FDA learned duodenoscopes could remain contaminated even after proper cleaning and the first safety alerts, at least 68 patients in seven different hospitals in the United States were infected with antibiotic-resistant infections.

The investigation provides a vivid example of the failure of FDA's current system for tracking and monitoring the safety of medical devices on the market (the postmarket surveillance system). FDA's postmarket surveillance system relies too heavily on self-reporting from manufacturers and hospitals with competing priorities that weigh against full and fast disclosure of patient safety concerns. This passive postmarket surveillance system inhibits FDA's ability to quickly identify information related patient health and device safety. Until a system is implemented that allows FDA to independently monitor, track, and assess the performance of devices, the agency will not be able to adequately identify risks to patient safety from particular devices like duodenoscopes and move quickly to address those risks.

Many Hospitals Experienced Infections Linked to Closed-Channel Duodenoscopes

Senator Murray's staff investigation has revealed that outbreaks of antibiotic-resistant infections caused by deadly multidrug-resistant organisms spread by duodenoscopes were vastly more widespread than previously reported. In June 2015, when Senator Murray first sought information from Olympus, Pentax, and Fujifilm, the three manufacturers of duodenoscopes sold in the United States, the Food and Drug Administration (FDA) had recently announced that there had been at least nine outbreaks of infections related to duodenoscopes.³ According to documents provided to the Health, Education, Labor, and Pensions (HELP) Committee, however, from 2012 through spring of 2015, there have actually been at least 25 separate outbreaks of patient infections following endoscopic retrograde cholangiopancreatography (ERCP) procedures with closed-channel scopes in four different countries and 10 states. These outbreaks infected at least 250 people with life-threatening illnesses including carbapenem-resistant Enterobacteriaceae (CRE), a dangerous superbug that is resistant to our most potent antibiotics and that kills about half of those it infects.⁴

Institutions where antibiotic-resistant infections linked to duodenoscopes occurred include:¹

¹ The number of patients infected and date of infections indicate committee staffs' understanding based on the totality of the information obtained during this investigation. They are <u>estimates only.</u>

Hospital	Estimated # of Patients Infected	Approximate time infections	Duodenoscope Manufacturer
Erasmus Medical Center, Rotterdam, Netherlands	30	January 2012	Olympus
Clinique De Bercy, Charenton-le-Pont, France	3	October 2012	Olympus
University of Pittsburgh Medical Center Presbyterian Hospital, Pittsburgh, PA	13 ⁵ November 2012		Olympus
New York-Presbyterian/Weill Cornell Medical Center, New York City, NY	15	December 2012	Olympus
UMass Memorial Medical Center, Worchester, MA	20	December 2012	Olympus
Carolinas Medical Center, Charlotte, NC	1	2013	Olympus
Thomas Jefferson University Hospital, Philadelphia, PA	8	January 2013	Olympus
Charite-Universitatsmedizin, Berlin, Germany	5	February 2013	Olympus
Advocate Lutheran General Hospital, Park Ridge, IL	32	March 2013	Pentax
Froedtert Hospital, Milwaukee, WI	5	May 2013	Olympus
Virginia Mason Hospital and Medical Center, Seattle, WA	32	Spring/Summer 2013	Olympus
Clinique De Bercy, Charenton-Le-Pont, France	2	November 2013	Olympus
Hartford Hospital, Hartford, CT	12	January 2014	Olympus
Massachusetts General Hospital, Boston, MA	7	Before Spring 2014	Pentax
Advocate Good Samaritan Hospital, Downers Grove, IL	3	May 2014	Fujifilm
Evangelisches Waldkrankenhaus, Spandau, Berlin, Germany	4	May 2014	Olympus
Boca Raton Regional Hospital, Boca Raton, FL	96	August 2014	Olympus
Cedars-Sinai Medical Center, Torrance, CA	4	August 2014	Olympus
UCLA Medical Center, Los Angeles, CA	7	October 2014	Olympus

Carolinas Medical Center, Charlotte, NC	18	2015	Olympus
MGH Gastroenterology Associates, Boston, MA	5	January 2015	Pentax
Massachusetts General Hospital, Boston, MA	3	January 2015	Pentax
Universitair Medisch Centrum, Utrecht, Netherlands	8	January 2015	Olympus
Allegheny General Hospital, Pittsburgh, PA	1	February 2015	Olympus
Fox Chase Cancer Center, Philadelphia, PA	3	April 2015	Fujifilm

Because some of the infections identified had unique markers that made the bacteria possible to track, and because the hospitals that have reported infections are primarily large, well-resourced research hospitals adept at spotting and addressing antibiotic-resistant infections, it is likely that there have been more incidents of infections linked to these devices that were never identified.

Background

Duodenoscopes, Reprocessing, and Automated Endoscope Reprocessors

Duodenoscopes are flexible, hollow tubes that are typically used during ERCP to treat patients suffering from blockage in their bile or pancreatic ducts due to tumors and other serious medical conditions.⁷ Doctors in the United States performed more than 660,000 potentially lifesaving ERCP procedures in 2014.⁸ Duodenoscopes are currently sold in the United States by three companies based in Japan: Olympus, Fujifilm, and Pentax. Olympus manufactures about 85 percent of the duodenoscopes used in the United States, Pentax about 12 percent, and Fujifilm only about three percent.⁹

All types of endoscopes can spread infection by passing bodily fluids or debris from one patient to subsequent patients if they are not properly cleaned between uses. Careful cleaning is especially critical for duodenoscopes because they are used in parts of the body with high levels of bacteria and patients undergoing procedures with duodenoscopes are often already very ill, raising the risk of infection. Also, a duodenoscope's elevator channel, which allows physicians to insert a guidewire and catheter into the duodenum, is particularly difficult to clean between uses. In early duodenoscopes, the elevator wire channel was open and exposed to bodily fluids, while the newer "closed-channel" duodenoscope model seals off the elevator wire channel from contaminants.¹⁰



Picture taken from www.olympus.co.uk

To ensure that a duodenoscope does not spread infection, it must undergo reprocessing, a multistep cleaning procedure to ensure the device is safe for re-use.¹¹ There are generally three steps to duodenoscope reprocessing:

- 1) <u>Point-of-use Processing:</u> Hospitals perform point-of-use processing immediately after a device has been used by rinsing or wiping the device to make sure that contaminants do not dry and make cleaning more difficult.¹²
- 2) <u>Thorough Cleaning</u>: After point-of-use processing, a technician uses a brush to ensure all parts of the device are cleansed of any soil and debris. Thorough cleaning is essential because debris and other material remaining on a duodenoscope can interfere with the final disinfection or sterilization phase of reprocessing.¹³
- 3) <u>High Level Disinfection</u>: Devices like duodenoscopes that contact mucous membranes or non-intact skin, but that cannot withstand heat sterilization, are required to undergo high level disinfection (HLD), which kills most microbes remaining after thorough cleaning.¹⁴ Most hospitals achieve HLD by using an AER. AERs flush liquid chemicals through the scope to destroy lingering contamination after cleaning and then rinse the scope to remove the chemical before reuse.¹⁵

FDA's Regulation of Devices

FDA oversees the safety and effectiveness medical devices, more than 1,700 of which are classified by the agency into three different categories based on the amount of risk they pose to patient health and safety.¹⁶ Duodenoscopes are classified as Class II devices, which pose a medium level of risk.¹⁷ When a manufacturer modifies the design of a Class II device in a way that might implicate the safety or effectiveness of that device, it must make what is known as a "510(k) submission" to show FDA that the device remains "substantially equivalent" to a device the agency has already cleared and that the design change does not put patients at any additional risk.¹⁸ It is the manufacturer's responsibility to determine when a 510(k) submission to FDA is required.¹⁹

It is also the manufacturer's responsibility to validate the design of their new or modified devices to make sure they work properly, which includes the ability for that device to be safely reprocessed between uses.²⁰ Manufacturers must test their devices and collect evidence to show that reprocessing will consistently result in a device that meets certain decontamination specifications.²¹ Proper validation should test all stages of reprocessing, and "the characteristics of the user population and operating environment [should be] considered."²²

Once a medical device is sold and in use in the United States, FDA monitors the device primarily by relying on manufacturers and hospitals to observe when a device is working and to report when it is not. Manufacturers are required to submit medical device reports (MDRs) within 30 days of learning information that reasonably suggests a device may have caused or contributed to a death or serious injury.²³ Within in 10 work days, hospitals must report serious injuries potentially caused by devices to the manufacturers, and report deaths connected to a device to both the manufacturers and FDA.²⁴ Additionally, the Medical Product Safety Network (MedSun) provides a secure online mechanism for 250 participating hospitals to report adverse events related to medical devices before a patient is injured or dies.²⁵ Finally, anyone, including hospitals and patients, may submit a voluntary "MedWatch" report to alert FDA to any suspected device issues.

FDA receives over one million MDRs each year, and relies on a small number of human reviewers to spot safety issues.²⁶ MDRs are often incomplete and lack key details, in part because FDA encourages quick filing with additional follow-up as more information is learned, and thus expects

initial submissions to be incomplete. MDR reports are primarily useful once FDA has already identified a problem; the agency can then search the MDR databases to identify similar or related reports. MDRs are extremely difficult to search and query, however. A simple spelling error or inconsistency in naming products can prevent the agency from tracking or identifying MDRs related to specific devices or patient outcomes.²⁷ Moreover, MDRs are not designed to identify trends, alert FDA to emerging problems, or track particular devices over time.

Finally, FDA can also require device manufacturers to conduct a postmarket surveillance study of the safety or effectiveness of a device (a section 522 postmarket surveillance study). FDA sets out specific questions, and the manufacturer designs and conducts a study to answer those questions over a three year period. The manufacturer then produces a Postmarket Surveillance Study Report setting forth the results of its study.²⁸ These section 522 postmarket surveillance studies have been criticized by some observers because there is very little infrastructure developed to assist device manufacturers as they design and carry out the studies, including a lack of device registries or identification codes that allow manufacturers to track and link devices to outcomes. ²⁹ Additionally, there are few incentives for clinicians and patients to participate in the studies, which may make it difficult for manufacturers to obtain the information they need.³⁰ As an example, while FDA has sought studies on 104 metal-on-metal hip products. However, just 24 products have FDA-approved study plans while the remaining 80 are listed as having either a "Plan Pending" or a "Plan Overdue.³¹

Currently, device manufacturers are essentially responsible for determining when a new clearance is required, how much information to report about adverse events, and how to conduct safety studies. This forces FDA to rely too heavily on manufacturers and user facilities to alert the agency to problems, help it accurately assess the severity of a potential safety issue, and move quickly to address it.

The Current Surveillance System to Ensure Medical Devices are Safe and Effective is Inadequate

The investigation found that FDA's current regulatory system for monitoring the safety of devices failed to quickly identify and resolve the spread of duodenoscope-linked, antibiotic-resistant infections. It took FDA almost a year and a half from the time the agency first became aware that closed-channel duodenoscopes could remain contaminated after proper cleaning to alert hospitals and the public. While responsibility for the slow response is shared among Olympus and the other device manufacturers, hospitals, and FDA, the investigation overall demonstrates that FDA's device surveillance system is overly-reliant on device manufacturers and user facilities to make quick and complete reporting of safety issues over their own competing priorities.

FDA relies on device manufacturers and hospitals to provide information so that FDA has the data it needs to assess the safety and effectiveness of medical devices. The regime relies on compliance with the law and self-reporting from device manufacturers and hospitals, ignoring the reality that manufacturers and health care providers have strong competing priorities that weigh against rapid and robust disclosure, such as moving new products to market quickly and avoiding costly litigation.

The current postmarket surveillance system relies on device manufacturers to self-monitor and self-report by: 1) determining when it is necessary to submit design modifications to FDA for review; 2) adequately testing that the devices work consistently in real-world settings; and 3) reporting when adverse events occur. The device manufacturers in this investigation failed to fully comply with any of these three regulatory requirements, providing a vivid example of the flaws with the current system.

FDA's reliance on manufacturers and hospitals to quickly and accurately report safety concerns related to devices stands in contrast to FDA's ability to independently monitor the safety of drugs. FDA increasingly has access to information about the postmarket safety and effectiveness of drugs through its "Sentinel" surveillance system.³² Because all drugs carry a National Device Code (NDC), which is also included on all pharmacy insurance claims and electronic health records, FDA has been able to leverage the wealth of information available through these sources to identify potential problems with a particular drug and proactively monitor drugs that are new to the market or are of particular interest. Sentinel allows FDA to query databases that contain real-time information, reducing the agency's reliance on the information reported by drug manufacturers and hospitals. Sentinel has the added advantage of allowing the agency to assess the frequency of adverse events relative to the overall use of a drug and relative to the rate of adverse events for similar drugs.

At this time, no similar system exists for devices. While the Food and Drug Administration Amendments Act of 2007 required devices to have a Unique Device Identifier (UDI) placed on medical device labels and packages comparable to the NDC number for drugs, and the Food and Drug Administration Safety and Innovation Act of 2012 required that Sentinel be expanded to devices, the UDI requirement does not go into effect for all devices until 2020.³³ Of more significant concern, UDIs are not currently included in insurance claims, which contain the critical information necessary to draw conclusions about device safety and patient outcomes. Without widespread adoption of UDI in electronic health records and claims, FDA will remain overly reliant on information reported by manufacturers and hospitals and unable to utilize a Sentinel-like system to ensure critical information about problematic devices is rapidly identified.

As detailed below, Olympus, Pentax, Fujifilm, and Custom Ultrasonics failed to report to FDA the information necessary to make the current postmarket surveillance system work properly. Hospitals also generally failed to provide manufacturers with required information about antibiotic-resistant infections linked to their devices or to proactively alert federal authorities to their concerns. As a result, FDA was unable to accurately assess and quickly react to the risks posed by closed-channel duodenoscopes.

Device Manufacturers Failed to Meet Regulatory Requirements and Endangered Patients

By the end of 2012, at least one duodenoscope manufacturer, Olympus, was aware that the new closed-channel duodenoscope the company had marketed since 2010 had the potential to remain contaminated even after cleaning and reprocessing according to manufacturers' instructions. Properly cleaning reusable devices like duodenoscopes is challenging, and failures to clean the devices correctly have resulted in patient infections in the past. An elevator wire channel located at the end of the duodenoscope allows doctors to move tools inserted through the duodenoscope

to perform procedures.³⁴ In early duodenoscope models, the elevator wire channel remained open and exposed to the same type of contamination as the rest of the scope.

In an effort to protect this part of the scope from contamination, in 2010 Olympus introduced a new closed-channel model that sealed off the elevator wire channel with an "O-ring" designed to prevent exposure to any contaminants from a patient. ³⁵ The other two duodenoscope manufacturers, Pentax and Fujifilm, similarly moved to closed-channel duodenoscopes although Pentax did so considerably earlier.

After a lengthy investigation by FDA throughout 2014 and 2015, it is now evident that, unlike open-channel duodenoscopes, closed-channel duodenoscopes can trap and transmit bacteria even when the devices are cleaned according to manufacturers' instructions. Moreover, at least one manufacturer, Olympus, the manufacturer of 85 percent of the duodenoscopes used in the United States and in 19 of the 25 reported incidents, was aware of the problems well before FDA's findings, but failed to adequately alert either FDA or the hospitals and patients using these scopes.

Olympus knew in 2012 that the design of its closed-channel duodenoscope could prevent effective cleaning.

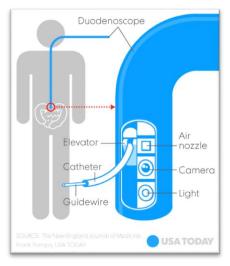
Erasmus Medical Center, Rotterdam, Spring 2012

In January 2012, there was an outbreak of antibiotic-resistant infections affecting 30 patients at Erasmus Medical Center in Rotterdam, the Netherlands. Hospital staff traced the infections to patients undergoing ERCP, and then directly to an Olympus TJF-Q180V closed-channel scope first marketed in the United States in mid-2010.³⁶

After Erasmus contacted Olympus, the hospital and manufacturer jointly asked Dr. Arjo Loeve of the Delft University of Technology to conduct an independent investigation into the Olympus

duodenoscope.³⁷ Dr. Loeve's investigation took place on April 23, 2012, at Olympus Netherlands headquarters with assistance from an Olympus employee flown in for the purpose of correctly disassembling the scope.³⁸ The investigation was observed by two Olympus Europa employees, three Olympus Netherlands employees, and six staff from Erasmus Medical Center.³⁹

The study identified two critical design flaws in the TJF-Q180V duodenoscope that made it difficult to clean reliably. First, Dr. Loeve found a series of tiny crevices that are too small to clean with a brush but large enough to allow in and trap bodily fluids and bacteria. In his report, Dr. Loeve points in particular to the space created by the axial clearance of the elevator, the area behind the curve of the elevator, and the hinges of the elevator as "locations where lingering and/or increasing moisture and/or biological materials are quite likely."⁴⁰



Picture from USA TODAY

Dr. Loeve also found that poor-quality sealing at the end of the scope is a potential mechanism for transmitting bacteria between patients. Dr. Loeve describes cracks in the material around the

camera, scale that was found behind the glass that covers the camera face, and open air bubbles, which can trap contaminants.⁴¹ The O-ring, which seals off the elevator channel from contamination, was torn, worn, and contained "brownish scale," which indicates the O-ring may not have created a tight seal.⁴² This is particularly dangerous because the closed elevator wire channel, unlike the open channel of the previous duodenoscope model, does not undergo HLD. Dr. Loeve concluded that it was "very likely [the] O-ring has not done its job" and "reliable sealing by means of the O-ring cannot be guaranteed."⁴³

Ultimately, in his May 2012 report, Dr. Loeve concluded that there needed to be a series of design changes to the TJF-Q180V scope to ensure it could be effectively decontaminated between uses. Dr. Loeve suggested changing the design of the scope to either have multiple sealing barriers or return to an open channel, to regularly ensure proper sealing between the O-ring and the scope, to frequently replace the O-ring to ensure the sealing mechanism remains functional, to alter the design to make various cracks and spaces larger so that a cleaning brush can reach them, and to rework the cleaning instructions to better address the hard-to-clean spaces in the scope.⁴⁴

On May 25, 2012, one month after five Olympus officials participated in the examination of the

"Reliable sealing by means of the O-ring cannot be guaranteed." *–Dr. Arjo Loeve* relevant scope at Delft University and ten days after the Delft report finding that the design of the scope hinders reprocessing was published, Olympus filed an MDR with FDA regarding the infections at Erasmus. The MDR stated that "the device was being investigated by independent organization [sic]" and that "the photograph of the distal end of the device which was sent

from OLYMPUS NEDERLAND showed the debris around the objective lens."⁴⁵ While the MDR provided FDA with notice that the infections were linked to the scope, it was fundamentally misleading. The MDR did not discuss the findings of the Loeve report, misstated the number of patients impacted, and specifically stated it could not "conclusively determine the cause [sic] this event," claiming that "it can be considered as a possible cause of this phenomenon that the patient infected from other than the endoscope and procedure such as environmental factor in the facility [sic]."⁴⁶

Following Dr. Loeve's report, the Dutch National Institute for Public Health and the Environment

(RIVM) requested additional documents and information from Olympus and Erasmus and produced a follow-up report in July 2013 that confirmed many of Dr. Loeve's findings.⁴⁷ The RIVM report agreed with Dr. Loeve that "the construction of the endoscope hinders optimum manual cleaning."⁴⁸ The RIVM report similarly confirmed that Olympus had no substantive response to Loeve's concern about the O-ring, although RIVM could not rule out that the scale seen by Loeve was a result of previous repairs made to the scope rather than O-ring failure.⁴⁹

"The construction of the endoscope hinders optimum manual cleaning." – *RIVM*

Olympus did not update FDA regarding the events at Erasmus Medical Center until March 2015, and the company still did not fully describe the findings of the Delft or RIVM reports.⁵⁰

University of Pittsburgh Medical Center Presbyterian Hospital, Pittsburgh, fall 2012

A few months after Dr. Loeve's report first raised alarms about whether the Olympus closedchannel duodenoscope could be consistently disinfected by following the manufacturer's cleaning instructions, Olympus was contacted by officials at the University of Pittsburgh Medical Center Presbyterian hospital in Pittsburgh, Pennsylvania ("UPMC").⁵¹ In the fall of 2012, UPMC experienced an outbreak of CRE, infecting about 13 patients who had undergone ERCP procedures with Olympus duodenoscopes.⁵² Repeated cultures of one particular duodenoscope by UPMC staff found bacteria in the biopsy and water channels even after the scope had been reprocessed three times.⁵³

After UPMC traced the infections back to the device, Olympus and an outside consulting group, ECRI Institute, evaluated UPMC's reprocessing procedures. ECRI found that UPMC's reprocessing was "consistent with standard practice and manufacturer recommendations."⁵⁴ ECRI told UPMC officials that it could not make a "definitive" assessment about whether "there is a defect within the endoscope that would provide a reservoir for bacteria" because the small crevices in the scope made it impossible for ECRI to fully examine the device.⁵⁵

When Olympus officials raised the possibility that the hospital's Custom Ultrasonics AERs could be at fault, UPMC officials went so far as to purchase an Olympus AER and demonstrated that the use of Olympus' own reprocessing machine did not prevent scopes from remaining contaminated after cleaning.⁵⁶ On December 18, 2012, Olympus filed an MDR with FDA, which documented some of the events at UPMC and the findings of ECRI. This MDR appears to have never been entered into FDA's system.⁵⁷

Additional independent testing, Jan 2013-2014

Documents obtained from Olympus show that from December 2012 through at least the summer of 2014 the company engaged independent laboratories to test company's closed-channel duodenoscopes for contamination, to assess whether the devices could be consistently disinfected, and to validate revised cleaning procedures. On January 8, 2013, before the infections at Virginia Mason had occurred, the French medical device evaluation company Biotech-Germande completed a report evaluating the Olympus duodenoscope with the same serial number as the scope involved in the December 2012 infections at Clinique de Bercy in France. The evaluation showed that "three cleaning/disinfection procedures were needed to eliminate the contamination that was initially present in the internal channels of the endoscope" and noted the "difficulty of eliminating all contamination present at the air/water and suction/biopsy valves and the operator channel cap through the application of a standard manual cleaning/disinfection procedure."⁵⁸ A follow-up study in July 2014 further confirmed "that after a complete reprocessing procedure consistent with the guidelines of the Ministry of Health and the recommendations of [Olympus] a contamination may persist at the distal end of the endoscope⁷⁵⁹ Studies at Bonn University conducted from March to November 2013, did confirm that a separate closed-channel duodenoscope was successfully cleaned using an Olympus AER.⁶⁰

European Alerts

By the end of 2012, Olympus had two clear examples of contaminated scopes spreading antibioticresistant infections even after correct reprocessing but neglected to alert hospitals or regulators in the United States. While Olympus left American doctors and hospitals in the dark about the duodenoscope design issues, in January 2013, Olympus sent a letter informing some European hospitals that they needed to carefully follow all reprocessing instructions and to "pay particular attention to the detailed pre-cleaning instructions, especially for the distal end and forceps elevator."⁶¹ By the time Olympus sent the letter, the company was aware of at least three duodenoscope-linked outbreaks impacting about 46 patients in three different countries; however, the letter only references "*a recently reported case*" of a contaminated TJF-Q180V scope.⁶²

Again, in August 2014, Olympus disseminated in Europe an urgent field safety corrective action. The August 2014 safety communication references "*a few* complaints of residual debris in the distal end of the TJF-Q180V duodenoscope after reprocessing."⁶³ By that time, Olympus knew of at least ten different instances of hospitals reporting contaminated TJF-Q180V scopes spreading antibiotic-resistant infections between patients.⁶⁴

FDA Investigation

In September 2013, after CDC alerted FDA to an outbreak of infections at Advocate Lutheran General Hospital linked to a Pentax duodenoscope, and CDC confirmed that Advocate Lutheran reprocessed scopes correctly according to the manufacturer's instructions, FDA began an investigation into closed-channel duodenoscopes. Throughout 2014, FDA worked to better understand the extent of the problem and to develop recommendations. It appears that at the time the investigation was initiated, FDA was unable to locate either the Erasmus or UPMC MDRs filed by Olympus and was without the benefit of reports from Dr. Loeve's Delft University or RIVM. By April 2014, FDA had independently sought validation data from the duodenoscope manufacturers in order to determine if the cleaning instructions worked reliably. FDA became aware of and obtained a copy of the Delft report only sometime after September 2014; had Olympus shared the existence of the report earlier, it likely would have sped FDA's investigation and led to more rapid alerts from both Olympus and the agency.

Instead, Olympus did not acknowledge the problem in the United States until February 19, 2015, six months after the urgent safety communication in Europe and almost three years after the Delft report. In May 2015, Olympus provided additional updates to their reprocessing instructions and distributed a new brush to help ensure that duodenoscopes are clean before undergoing HLD – a brush that was available in Europe for nearly five years before it was provided in the United States. Had hospitals been alerted to the risk and the need to use increased efforts to ensure that duodenoscopes were appropriately disinfected, some if not all of the infections, including in Seattle, may have been prevented.

Olympus's failure to take action and alert regulators likely contributed to the at least 141 patient infections linked to Olympus duodenoscopes that occurred in domestic hospitals between the spring of 2012, when Olympus was well aware of potential flaws with the device, and February of 2015, when the company finally alerted doctors and hospitals in the United States.

Olympus failed to meet its regulatory obligations.

Olympus's failure to act upon the information it knew about the problems decontaminating closedchannel duodenoscopes and the spread of deadly infections is consistent with the company's failure to meet its obligations at each step of the device regulatory process. During its investigation in 2014 and 2015, FDA determined that Olympus failed to seek required clearance for the modification from an open to closed-channel device, failed to validate the closed-channel duodenoscope cleaning instructions to make sure they worked consistently, and failed to fully report information it knew about the adverse events linked to its device.

Olympus did not clear its duodenoscope design modification with FDA.

Manufacturers of Class II devices like duodenoscopes are required to make a 510(k) submission in order to market a new device, an existing device for a new purpose, or a device that is changed or modified in a way that might implicate its safety or effectiveness.⁶⁵ This allows FDA to ensure that the modified device remains "substantially equivalent," or at least as safe and effective, as a device that is already legally on the market.⁶⁶ It is the manufacturer's responsibility to determine if and when a 510(k) application should be submitted to FDA.⁶⁷

Olympus did not file a 510(k) application for the TJF-Q180V duodenoscope because it determined the new model was similar to a previous device, the TJF-Q160, approved in 2008. However, unlike the TJF-Q180V, the TJF-Q160 has an open elevator wire channel. FDA subsequently determined Olympus was wrong to assert that the TJF-Q160 and TJF-Q180V are substantially equivalent devices, and found that the change from an open to a closed elevator channel "impacts the safe use of the device" because the newly sealed elevator channel "prevent[s] sterilization and high level disinfection."⁶⁸ FDA notified Olympus that it should have made a 510(k) submission to account for the substantial changes between the TJF-Q160 and the TJF-Q180V and, in March 2014, required the company to belatedly make that submission. FDA is currently in the process of evaluating those documents to assess the substantial equivalency of the elevator channel sealing mechanism.

Olympus failed to ensure duodenoscope cleaning instructions worked before selling closedchannel duodenoscopes to hospitals.

The investigation also found that Olympus has been selling its closed-channel duodenoscope since 2010 without sufficiently testing its cleaning instructions to ensure that they actually work in real-world settings, and that Olympus knew that its testing data was insufficient since at least 2013.

FDA requires device manufacturers to validate the design of their devices, which includes the ability for that device to be safely reprocessed between uses.⁶⁹ In other words, manufacturers must test their devices and collect evidence to show that reprocessing will consistently result in a device that meets certain decontamination specifications.⁷⁰ Proper validation should test all stages of reprocessing and should consider "the characteristics of the user population and operating environment."⁷¹

However, in July 2013, following the infections at Erasmus Medical Center in Rotterdam, RIVM examined Olympus' validation of the TJF-Q180V reprocessing instructions and found the data analysis "unacceptable as a demonstration of effective cleaning."⁷² RIVM concluded that the data Olympus provided to show that manual cleaning could decontaminate the elevator mechanism

"left so much to be desired that it is not possible to support the conclusion drawn by the manufacturer, namely that the cleaning and disinfection procedure for the elevator is effective." ⁷³ Olympus also did not provide RIVM with information to substantiate that the O-ring effectively seals the elevator wire channel from contamination or attempt to show

[Olympus's reprocessing data] is "unacceptable" and left so much to be desired that it is not possible to support the conclusion . . . that the disinfection procedure. . . is effective." - *RIVM*

that the leak testing that hospitals are supposed to conduct during reprocessing is an accurate way of assessing when an O-ring is wearing out and in need of maintenance from the manufacturer.⁷⁴ After requesting Olympus's validation data in April 2014, FDA reached the same conclusion –

Olympus did not have sufficient data to show closed-channel duodenoscopes could be reliably cleaned with an adequate margin of safety.

In the 19 months between RIVM's conclusion that Olympus did not have sufficient validation data and Olympus' first safety notice, at least 49 patients in the United States were infected with antibiotic-resistant bacteria connected to an Olympus closed-channel duodenoscope.

At the time Olympus' closed-channel duodenoscopes were first sold in the United States, FDA relied on manufacturers to attest that their devices had been validated effectively before being marketed. Unsurprisingly in view of the RIVM findings, in April 2014 when FDA similarly asked Olympus to produce suitable data to show their cleaning instructions actually worked, the company could not do so.⁷⁵ The faith that patients, doctors, hospitals, and public health officials placed in Olympus to thoroughly test their cleaning instructions before putting devices in the marketplace was clearly misplaced.

In February 2015, Senator Murray requested FDA update its draft reprocessing guidance for reusable devices, and on March 17, the agency issued final guidance, "*Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*." ⁷⁶ This final guidance requires manufacturers of high-risk reusable devices such as duodenoscopes to provide FDA with their actual reprocessing data when applying for clearance to market devices so that FDA can assess the validity of cleaning instructions for itself. While the guidance is a useful step, under current law, manufacturers of reusable devices are still not required, as a condition of market clearance, to produce data that actually demonstrates the devices can be reliably and repeatedly cleaned in real world conditions.

Olympus submitted incomplete and misleading medical device reports to FDA.

Finally, while Olympus generally submitted MDRs to account for duodenoscope-linked infections the company was aware of, Olympus did so in such a cursory manner as to make it nearly impossible for the agency to accurately assess the scope and severity of the infections liked to duodenoscopes. Because device manufacturers and importers are the only entities required to submit adverse event reports to FDA when a device is linked to a serious injury, the agency relies heavily on the accuracy of manufacturers' reports to track problems with medical devices.⁷⁷

Some Olympus MDRs, particularly those submitted for outbreaks in Europe, understate the number of patients affected,⁷⁸ point to environmental contamination as a source of the infections rather than problems with the device itself,⁷⁹ and fail to provide the full information available to Olympus. Following the reports of contaminated scopes at Erasmus Medical Center and Clinique de Bercy in France, Olympus received results from independent labs that found the duodenoscopes linked to infections in those hospitals could contain bacteria even after being cleaned correctly, but never updated their adverse event reports or communicated that information to FDA.

As a result of inspections conducted in 2015, FDA found that Olympus "fail[ed] to adequately develop, maintain, and implement written MDR procedures" as mandated by adverse event reporting regulations and did not have a consistent process for "submit[ting] all information reasonably known to it for each event."⁸⁰ While FDA's findings regarding the MDRs submitted by Olympus are certainly correct, the violations also understate the real impact of Olympus' larger failure to alert regulators in the United States and Europe about significant problems in cleaning the TJF-Q180V closed-channel scope.

Pentax and Fujifilm also failed to comply with regulatory requirements.

While the majority of the infections that occurred between 2012 and spring of 2015 were connected to an Olympus duodenoscope, closed-channel devices manufactured by Pentax and Fujifilm were also linked to six outbreaks and at least 53 antibiotic-resistant infections during this time. Pentax sells about 12 percent of the duodenoscopes used in the United States and Fujifilm about three percent.⁸¹ These duodenoscope manufacturers contributed to the dangerous superbug and other antibiotic-resistant infections linked to ERCP procedures at hospitals in the United States and around the world by failing both to comply with the same basic regulatory expectations as Olympus and communicate thoroughly with FDA about the outbreaks.

Fujifilm failed to clear their duodenoscope design modifications with FDA.

Similar to Olympus, FDA determined that Fujifilm never made a 510(k) submission for the modifications in the design of its closed-channel scope ED-530XT.⁸² Fujifilm had concluded that there were only minor changes between ED-530XT and the already-approved open-channel model ED-450XT5. However, FDA's inspection identified least four potentially substantial differences between the ED-450XT5 and the ED-530XT. In August of 2015, FDA sent a 510(k) status letter to Fujifilm summarizing these findings and requested a 510(k) application for the ED-530XT.⁸³ FDA has not yet determined whether Pentax should have submitted a 510(k) application to account for the changes between the Pentax ED-3490TK and ED-3670TK.⁸⁴

Pentax and Fujifilm failed to properly validate their duodenoscope reprocessing instructions.

Once FDA launched its investigation into closed-channel duodenoscopes, it requested the data from Pentax and Fujifilm demonstrating that each company's closed-channel duodenoscope could be consistently cleaned. Also like Olympus, both Pentax and Fujifilm were unable to produce the required underlying data to show that the cleaning instructions were consistently effective. In fact, after FDA inspections of Fujifilm plants in April and May 2015, the agency observed multiple flaws in Fujifilm's validation process including that the company did not evaluate the O-ring,⁸⁵ performed validation on a mock-up of a duodenoscope channel rather than the actual device,⁸⁶ did not produce the appropriate reduction in bacterial spores during ethylene oxide sterilization validation,⁸⁷ and did not evaluate the design of the closed-channel model under actual or simulated conditions of use.⁸⁸

FDA inspections also found that Pentax had validated its HLD and sterilization protocols for the ED-3670TK duodenoscope using an entirely different model of scope and could not show that the two duodenoscopes responded comparably to reprocessing.⁸⁹ Moreover, Pentax tested sterilization of the scope with a different mixture of gas than it instructed hospitals to use.⁹⁰

On December 23, 2015, FDA announced that new Fujifilm reprocessing instructions that included additional brushing, washing, and flushing were sufficiently validated, and "demonstrate consistent and reliable cleaning and high level disinfection."⁹¹ Meanwhile, Pentax has not yet demonstrated to FDA that its new cleaning instructions were validated, leaving doctors and hospitals in the disconcerting position of using a device without cleaning instructions they can feel confident about.

Pentax and Fujifilm submitted late and incomplete medical device reports.

Similarly, Fujifilm and Pentax failed to meet their obligations to self-report serious illnesses and deaths that may have been caused by their duodenoscopes. After inspecting manufacturers' files in 2015, FDA found that both companies had substandard MDR reporting practices. Pentax failed to "adequately develop, maintain, and implement written MDR procedures" or "internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements."⁹² Meanwhile, Fujifilm lacked procedures for "receiving, reviewing, and evaluating complaints."⁹³

These failures may well explain why neither Fujifilm nor Pentax appears to have filed a single adverse event report related to antibiotic-resistant infections and closed-channel duodenoscopes with FDA for any incidents in any foreign country until the fall of 2015 despite the regulatory requirement to report adverse events that occur anywhere in the world for any device sold in the United States.⁹⁴ The Americas are only about 36 percent of Pentax's business worldwide with 15 percent in the Asia Pacific region, 49 percent in Europe, the Middle East, and Africa, and less than one percent in Japan.⁹⁵ Fifty percent of Fujifilm duodenoscopes are sold in Europe, 22 percent in Asia, and 18 percent in Latin and South America.⁹⁶ Since Pentax and Fujifilm scopes were collectively linked to six outbreaks domestically by Spring 2015, it is hard to imagine that no infections during this time were connected to the more than 90 percent of Fujifilm scopes in use outside of North America and more than 64 percent of Pentax duodenoscopes used outside of North and South America.

Overall, FDA inspections documented that all three duodenoscope manufacturers put patients' lives in jeopardy by failing to meet their obligations at each step of the regulatory process. The manufacturers failed to seek FDA clearance for their modified devices when they changed to the closed-channel design. When confronted with evidence that the design of closed-channel duodenoscopes was contributing to the spread of infections across the United States and worldwide, the duodenoscope manufacturers did not take adequate action to alert device users or regulators, allowing its device to spread superbug and other serious infections among ERCP patients for years.

Custom Ultrasonics' automated endoscope reprocessors likely contributed to patient infections.

On November 13, 2015, FDA took the unusual step of issuing a mandatory recall of all of the approximately 2,800 Custom Ultrasonics AERs in hospitals and clinics across the United States. FDA is so concerned about Custom Ultrasonics AERs' ability to perform as marketed that the agency deemed a mandatory recall necessary to protect the public's health, and has recommended that hospitals using Custom Ultrasonics AERs switch to alternative methods of HLD.⁹⁷

HELP Committee staff has been able to confirm that Custom Ultrasonics machines were used by at least nine out of 16 domestic hospitals that experienced infections after ERCP procedures accounting for about 141 patient infections at:

- UPMC Presbyterian Hospital, Pittsburgh, PA
- NYP/Weill Cornell Medical Center, New York City, NY
- UMass Memorial Hospital, Worchester, MA
- Advocate Lutheran General Hospital, Park Ridge, IL
- Hartford Hospital, Hartford, CT
- Massachusetts General Hospital, Boston, MA
- UCLA Medical Center, Los Angeles, CA
- Carolinas Medical Center, Charlotte, NC
- Thomas Jefferson University Hospital, Philadelphia, PA

Considering that only about ten to 20 percent of the AERs used in American hospitals are Custom Ultrasonics AERs, it appears the defective machines played a significant role in allowing the duodenoscopes to remain contaminated between uses.

However, it is also clear that duodenoscope-linked infections cannot be solely attributed to Custom Ultrasonics machines. Erasmus Medical Center, Virginia Mason Hospital, Froedtert Hospital, and Advocate Good Samaritan Hospital all experienced contaminated duodenoscopes while using other brands of AER machines. Additionally, UPMC, which used Custom Ultrasonics machines, took the unusual step of purchasing an Olympus-made AER and demonstrated that their Olympus closed-channel duodenoscope remained contaminated even after cleaning it in Olympus' own AER.

Similar to washing machines, AERs flush liquid chemicals through scopes to destroy lingering contaminants after the device is hand cleaned with small brushes in order to achieve HLD. If an AER is not working correctly, it may not completely disinfect the scopes. Custom Ultrasonics' AERs do not appear to have consistently provided HLD when used to clean duodenoscopes after procedures, and the company, like the duodenoscope manufacturers, appears to have repeatedly abused the expectations of the current regulatory system.

FDA first cleared the Custom Ultrasonics AER for use in 1984 but the company has faced regulatory challenges dating back to at least 2005.⁹⁸ After FDA inspections in 2005-2007 revealed that Custom Ultrasonics failed to comply with regulations designed to ensure that devices are manufactured according to certain standards of quality, Custom Ultrasonics and FDA entered into a consent decree in 2007 preventing Custom Ultrasonics from manufacturing and distributing any devices – including AERs.⁹⁹ Although the company was able to resolve some of the issues and resume manufacturing five months later, FDA subsequently found Custom Ultrasonics in violation of the terms of the consent decree at least three separate times since 2008, including failure to seek 510(k) clearances for significant changes to its devices.¹⁰⁰

In the spring of 2015, FDA asked for data from all AER manufacturers. In April 2015, an inspection of the Custom Ultrasonics plant in Ivyland, Pennsylvania found Custom Ultrasonics:

Never validated the compatibility of its AERs with closed-channel models of duodenoscopes;



Picture from www.customultrasonics.com

- > Did not validate their AERs with specific types of HLD cleaning solutions;
- Did not validate the effectiveness of pre-filters that prevent large particulates and debris from contaminating devices; and
- > Did not sufficiently validate the water filtration system.¹⁰¹

Ultimately, FDA concluded that Custom Ultrasonics machines could not consistently provide the adequate margin of safety required by liquid chemical sterilant and HLD-specific guidance.¹⁰²

Overall, the investigation found that the current regulatory regime places obligations on device manufacturers that each of the four manufacturers above repeatedly failed to meet. At each step of the regulatory process – the determination of whether new device clearances need to be sought, quality testing that truly proves a device will consistently perform in real world settings, and prompt and complete reporting of all required adverse events – each of the four device manufacturers discussed above failed to meet these obligations. These failures are directly responsible for the spread of antibiotic-resistant infections in already critically ill patients.

Hospitals Were Slow to Report Infections

While this investigation has demonstrated that duodenoscope manufacturers and Custom Ultrasonics failed to quickly and comprehensively report problems with their devices to FDA, the investigation has also revealed a similar problem among hospitals. At least 16 domestic hospitals, primarily large, sophisticated health systems, identified outbreaks of antibiotic-resistant infections linked to ERCP, but none actually followed all of the required steps to promptly notify manufacturers or, in cases of death, FDA.

FDA regulations require hospitals to submit an adverse event report to a device manufacturer within ten working days of becoming aware of information that reasonably suggests that a device "may have caused or contributed" to a serious injury or death.¹⁰³ The hospital is supposed to report the information to the manufacturer on FDA form 3500A or an approved electronic substitute, which includes a variety of information about the facility, the patient, and what happened, in order to help the manufacturer meet their own reporting obligations to FDA.¹⁰⁴

Because they are on the front lines of treating patients, doctors and hospitals are often the first to recognize device related problems. Health care providers thus play a critical role in alerting manufacturers and federal regulators to suspected issues. However, conversations between Senator Murray's HELP Committee staff and hospital staff, state and local health departments, and manufacturers have revealed a disconcerting lack of awareness that these reporting obligations even exist.

Hospitals did not comply with mandatory requirements to report information to manufacturers.

As part of this investigation, HELP Committee staff spoke with staff at eight hospitals that had

infections linked to closed-channel duodenoscopes before or around September 2013 – when FDA first understood that some duodenoscopes remained contaminated after cleaning according to manufacturers' instructions.¹⁰⁵ These conversations demonstrated that numerous hospitals were able to identify, track, and contain superbug and other antibiotic-resistant infections within their hospitals, but not a single hospital that experienced infection outbreaks tied to the duodenoscopes appears to

It appears that not a single hospital that experienced infection outbreaks linked to the duodenoscopes sent the required adverse event form to the device manufacturers.

have sent the required adverse event form to the device manufacturers. Several hospitals appear to have failed entirely to alert the device manufacturer in any way.

Multiple hospitals across the country engaged in exemplary public health work to identify clusters of antibiotic-resistant infections, isolate the source, and contain the problem. At least 16 hospitals across the United States were able to identify that they had patients with unusual infections and trace those infections back to ERCP procedures performed with duodenoscopes. These investigations were often complicated and sophisticated. For example, Virginia Mason, with the assistance of the Washington State Department of Health, undertook enhanced surveillance efforts that identified a cluster of patients infected after ERCP. From that cluster, hospital officials were able to identify a unique isolate that was then used to trace the infections.

Similarly, UMass Hospital in Worchester, Massachusetts used isolate testing and DNA fingerprinting to confirm that liver transplant patients were infected with the same strain of antibiotic-resistant bacteria. Massachusetts General Hospital in Boston and NYP/Weill Cornell Medical Center in New York City conducted in-depth retrospective analyses that retroactively linked patient infections with ERCP procedures. It is likely that many hospitals with fewer resources similarly experienced infections but did not identify or track the infections.

Most hospitals also alerted either their state or local health departments about the infections. States have varying reporting requirements and not all hospitals are required to report infections to health department officials, or may be required only to report certain types of infections or infections impacting a large number of patients.¹⁰⁶ Even in cases when reporting was not required, however, hospitals generally appear to have communicated with their local or state officials about outbreaks. However, with the exception of Advocate Lutheran General Hospital, and Virginia Mason hospital which worked with a CDC staffer embedded in the King County Health Department who kept the agency informed, no hospital directly notified CDC, and there is no federal reporting requirement for hospitals to do so.

Startlingly, after identifying the source of the outbreaks, none of the eight hospitals entirely fulfilled their legal obligation to quickly alert manufacturers or FDA to adverse events at their hospitals traced to devices. Certain hospitals, including UMass, Carolinas Medical Center and Thomas Jefferson, failed entirely to alert manufacturers to problems, leaving Olympus, Fujifilm, Pentax, and FDA unaware of the outbreaks of infections potentially caused by contaminated duodenoscopes. Some hospital staff have explained they did not inform manufacturers, even after tracing infections back to ERCP procedures, because they could not demonstrate that a particular

scope harbored contamination, or be entirely certain that a problem with a specific duodenoscope caused a particular illness or cluster of infections among ERCP patients.

When hospitals did report adverse events, it was generally late, notification was made informally by phone or email, and reports did not include all of the information necessary for the manufacturers to submit accurate and complete information to FDA. Olympus relayed that none of the 12 domestic hospitals with outbreaks linked to Olympus scopes sent the required FDA form 3500A to the manufacturer.

Moreover, UPMC, NYP Weill/Cornell Medical Center, Advocate Lutheran, and Virginia Mason notified manufacturers of a potential problem months after they were aware of the connection. For example, by December 2013, Virginia Mason knew that duodenoscopes were contaminated and spreading antibiotic-resistant infections between patients but did not alert the manufacturer to the issue until July 2014.¹⁰⁷ When a team from Olympus evaluated Virginia Mason's reprocessing procedures in the fall of 2013, the hospital never mentioned the infections.¹⁰⁸ Hartford Hospital reported a patient tested positive for "bacterial micro-organisms" after an "unspecified procedure," vague information at best. Olympus followed up but received no response from the hospital.¹⁰⁹ Pentax MDRs also documented difficulty obtaining information from Massachusetts General Hospital, receiving no response after multiple requests for information.¹¹⁰

Overall, not one of the hospitals that had identified infection outbreaks by the time FDA became aware of the problem in September 2013 notified the manufacturer within the period dictated by FDA regulation.

Hospital	Notified the Manufacturer *	Notified FDA *	Notified CDC	Notified Patients	Notified State/Local Health Departments **
UPMC Presbyterian					
Hospital,	Late	Late	No	Unk	Yes
Pittsburgh, PA					
NYP Weill/ Cornell Medical Center	Late	Late	No	Unk	Yes
NYC, NY	Latt	Latt	110	UIIK	105
UMass Memorial					
Hospital,	No	No	No	Yes	Yes
Worchester MA					
Advocate Lutheran General Hospital,	Late	Yes	Yes	Yes	Yes
Park Ridge IL	Late	105	1 05	105	1 05
Froedtert Hospital, Milwaukee WI	Late	Unk	No	Unk	Unk
Virginia Mason Hospital and Medical Center, Seattle WA	Late	Late	Indirectly	Late	Late
Thomas Jefferson University Hospital, Philadelphia, PA	No	No	No	No	Yes

Carolinas Medical Center, Charlotte, NC	Unk	Unk	No	Unk	Unk
* Required ** May be required depending on the state					

Hospitals did not proactively communicate information to federal agencies.

Hospitals also generally failed to communicate directly with FDA and CDC. Hospitals are required to report information related deaths (but not serious injury) to FDA no more than ten days after becoming aware of the incident, and may always submit adverse event reports relaying other suspected problems to the agency.¹¹¹ While several hospitals did eventually submit MedWatch reports to FDA, less than one percent of all the adverse event reports were submitted by hospitals, suggesting that hospitals are not meeting their obligations to report deaths that devices may have caused or contributed to.¹¹² Moreover, hospital staff interviewed by Committee staff almost universally were unfamiliar with any obligation to report to FDA.

Even the hospitals that did file reports typically failed to provide FDA with a full picture of what they knew. For example, in its one-paragraph MedWatch report filed March 4, 2013, about five months after linking infections to duodenoscopes, UPMC reported that the "source of the [infection] remains undetermined at this time."¹¹³ The report included neither that UPMC's reprocessing procedures had been validated by Olympus nor that the hospital was unable to decontaminate the duodenoscope after multiple attempts at reprocessing. NYP Weill/Cornell filed a MedWatch report on October 9, 2013 clearly explaining that the duodenoscope could not be reliably cleaned, but filed the report seven months after identifying the duodenoscope elevator as a source of the infections.¹¹⁴ Virginia Mason also filed a MedWatch report but did so in May 2014, at least five months after connecting patient infections to duodenoscopes.¹¹⁵ No hospital that identified clusters of antibiotic-resistant infections linked to closed-channel duodenoscopes reported those infections to CDC until May 2013.¹¹⁶

Overall, hospitals' slow approach left FDA with an inaccurate picture of the frequency and severity of these events. Reporting by the hospitals as a whole suggests that rather than collaborate to quickly alert regulators to a potential device problem, hospitals were reluctant to share unconfirmed information. Hospitals as a whole appear to have believed they had an obligation to report only what they could demonstrate beyond any doubt. Such narrow reasoning reveals a misunderstanding about hospital reporting requirements, which are triggered by information that *reasonably suggests* a device *may* have caused or contributed to a death or serious injury.¹¹⁷ Hospitals' slow reporting may have had the effect of impairing FDA's initial understanding of the number and severity of infections tied to duodenoscopes, and is further evidence of the need to move beyond self-reporting to identify and address issues posed by medical devices.

FDA Failed to Recognize the Prevalence of Duodenoscope-Linked Infections and Respond Quickly

FDA first became aware that closed-channel duodenoscopes could not be reprocessed consistently to prevent transmission of deadly superbug and other antibiotic-resistant bacteria between patients in September 2013, after CDC alerted them to infections at Advocate Lutheran General Hospital. By this point, at least 11 hospitals, including Virginia Mason, had experienced outbreaks linked to reprocessed duodenoscopes. Because of FDA's reliance on a passive postmarket surveillance system, the agency had no way to identify this trend until the issue was directly brought to their attention.

FDA reviews reports filed by manufacturers and others largely by having staff with clinical backgrounds read the more than one million adverse event reports submitted every year.¹¹⁸ As discussed above, FDA does not flag incomplete reports because the agency expects MDRs to be filed before all the relevant information is known, and expects manufacturers to supplement the reports as they learn more. Therefore, it is challenging for reviewers to identify trends that might involve a relatively low number of incidents. Additionally, because there is no way to measure how a series of adverse event reports relate to the total number of devices and procedures, the system provides no way to assess the prevalence of adverse events.

In the spring of 2013 Advocate Lutheran General Hospital contacted CDC about an ongoing CRE outbreak, the only hospital to proactively contact the agency.¹¹⁹ CDC officials sent to the hospital in August 2013 were able to trace the infection back to the closed-channel Pentax duodenoscopes used in ERCPs *and* confirm that the scopes had been carefully reprocessed by the hospital.¹²⁰ CDC in turn alerted FDA that duodenoscopes were potentially transmitting bacteria even after being cleaned in accordance with the manufacturer's instructions.

At that point, FDA began an investigation into infections transmitted by closed-channel duodenoscopes. One of FDA's initial steps was to query their adverse event reporting system to determine if similar events had been reported elsewhere. When FDA initially queried its adverse event database after learning from CDC of the infections at Advocate Lutheran, FDA had received the following information about six outbreaks involving closed-channel duodenoscopes:

- 1) *Erasmus Medical Center, Rotterdam, Netherlands*. Notified in May 2012 that 16 patients had tested positive for Pseudomonas aeruginosa after undergoing an ERCP with an Olympus duodenoscope, and that an independent investigation was being conducted.¹²¹
- 2) **UPMC Presbyterian Hospital, Pittsburgh, PA.** Notified in November 2012 that ten to 13 patients may have been infected with CRE after undergoing a procedure with an Olympus duodenoscope.¹²² Also notified that CRE had been found on one of the scopes, and that the scopes tested positive for Klebsiella pneumonia on two separate occasions after multiple cultures. In October 2013, an additional report relayed that another scope tested positive for contamination.¹²³
- Clinique de Bercy, Charenton-le-Pont, France. Notified in December 2012 that three patients were infected with Escherichia coli after undergoing an ERCP performed with an Olympus duodenoscope. Mentions that the scope is being sent to an independent lab for testing.¹²⁴

- 4) *Charite-Universitatsmedizin, Berlin, Germany*. Notified in April and July 2013, that five patients at Charite-Universitatsmedizin in Berlin were infected with Klebsiella after undergoing treatment with an Olympus duodenoscope that had been used earlier on a patient with the same infection. Two of the five infected patients died.¹²⁵
- 5) *NYP/Weill Cornell Medical Center, NYC, NY*. Notified in June 2013 that 15 patients at NYP/Weill Cornell Medical Center were infected with CRE after undergoing a procedure with an Olympus duodenoscope and that four different duodenoscopes tested positive for CRE even after the scopes had undergone HLD. Olympus also reported the hospital was not using the correct reprocessing procedures.¹²⁶
- 6) *Advocate Lutheran General Hospital, Park Ridge, IL*. Notified in July 2013 that a patient had undergone ERCP with a Pentax closed-channel duodenoscope and then developed a CRE infection. The hospital confirmed that its staff used proper reprocessing procedures, and that an organism had been found under the elevator on the duodenoscope.¹²⁷

Taken together these reports should have provided FDA with considerable information to suggest cleaned scopes were continuing to spread infection; however, the agency appears to have lost the report filed describing the 2012 outbreak at UPMC (it is not available in the agency database). This left FDA without the key information that reported the earliest domestic antibiotic-resistant infections linked to a correctly reprocessed duodenoscope. It also appears that FDA's initial search of their adverse event report database did not identify the foreign adverse event reports that accounted for half of the incidents reported before September 2013. Accordingly, FDA's initial query may have left the agency with information about just one additional instance of closed-channel duodenoscope linked infections.

By the time FDA started its investigation, outbreaks of antibiotic-resistant infections had likely already occurred at Thomas Jefferson University, Virginia Mason, Carolinas Medical Center, and Froedtert hospitals. However, those outbreaks had not yet been reported to the agency, or, in some cases, to the device manufacturers. FDA appears to have been left with such incomplete information that it was unable to develop an accurate sense of the frequency and severity of these outbreaks. This lack of complete information made it difficult for the agency and outside experts to conclusively determine that mistakes in the cleaning and reprocessing of the duodenoscopes were not the source of the infections.

Throughout late 2013 and 2014, as the agency became aware of the clusters of infections in Pennsylvania, Massachusetts, Connecticut, Washington, Illinois, and Wisconsin, and the number of patients infected with potentially deadly bacteria continued to rise, FDA continued to investigate and collaborate with CDC and outside experts. FDA had not yet determined whether the infections occurred because hospitals did not correctly follow manufacturers' cleaning instructions or whether the closed-channel duodenoscopes could remain contaminated even after reprocessing was correctly carried out. FDA had also not yet developed supplemental reprocessing recommendations to ensure hospitals initiated enhanced cleaning procedures. As a result, FDA still had not issued any safety communication to alert hospitals to the risk posed by these devices.

In April 2014, FDA sought the validation data from duodenoscope manufacturers to show that they had properly tested their cleaning instructions to make sure that the data showed the instructions worked consistently. It was not until September 2014, when an FDA official met someone involved with the investigation of the outbreak in the Netherlands at a conference, that

FDA learned of the RIVM report detailing Olympus' lack of cleaning validation data almost a full year earlier. As a result, it took an additional year for FDA to receive the data, determine it was insufficient, and for the manufacturer to develop enhanced cleaning procedures cleared by FDA in the spring of 2015.

By late 2014, FDA had sufficient information to begin preparing a safety communication for hospitals. In January 2015, news reports revealed the infections in Seattle as well as more recent infections at UCLA and Cedar Sinai hospitals in California. On February 4, 2015, Senator Murray wrote to FDA seeking additional information about the infections, urging the agency to provide hospitals with safety information and to finalize the guidance for the cleaning of reusable devices that had been issued as a draft in 2010.¹²⁸

Following those events, U.S. federal agencies took the following steps in 2015:

- **February 19: FDA issues a Safety Communication.** FDA warns for the first time that duodenoscopes may transmit antibiotic-resistant infections between patients "even when manufacturer reprocessing instructions are followed correctly." ¹²⁹
- March: The Department of Justice (DOJ) launches a criminal investigation into duodenoscope manufacturers. DOJ has since issued subpoenas to Olympus, Fujifilm, and Pentax as well as several hospitals for information related to duodenoscopes and antibiotic-resistant infections.
- March 12: CDC issues an interim duodenoscope surveillance protocol. CDC issued an interim protocol that instructs hospitals about how to culture and quarantine devices to assess whether their reprocessing procedures and manufacturers cleaning instructions are working correctly, and to identify contaminated scopes before they are used during procedures.¹³⁰
- March 17: FDA finalizes reprocessing guidance for reusable devices. The finalized guidance makes clear that FDA expects to see in 510(k) applications underlying data demonstrating that cleaning instructions actually work for certain reusable devices, including duodenoscopes.¹³¹
- March–May: FDA inspects Olympus, Fujifilm, and Pentax manufacturing plants. The inspections noted failures to make requisite 510(k) submissions by Olympus and Fujifilm, failures to maintain adequate MDR reporting systems, and failures to properly validate cleaning instructions.
- April: FDA inspects Custom Ultrasonics' facility. Inspectors documented a series of violations including that the company had insufficient data to show their AERs worked effectively.
- May 15 and 16: FDA convenes a meeting of the Gastroenterology-Urology Device Advisory Committee. FDA issues an Executive Summary of the meeting indicating the agency is aware of at least nine outbreaks of infections linked to closed-channel duodenoscopes. The Advisory Committee discusses potential options for hospitals to ensure that devices are consistently cleaned after every procedure, including the culture and quarantine protocol developed and implemented by Virginia Mason staff.¹³² None of the three device manufacturers attended the advisory committee meetings.

- August 4: FDA issues a safety communication for supplemental reprocessing. The safety communication included four potential supplemental reprocessing measures including the microbiological culturing method put in place by Virginia Mason, Ethylene Oxide Sterilization, a liquid chemical sterilant processing system, or repeat HLD. None of these options are ideal. For example, ethylene oxide sterilization may pose health risks to hospital staff and microbiological culturing requires a hospital to purchase additional duodenoscopes.¹³³
- August 12: FDA issues warning letters to Fujifilm, Pentax, and Olympus. The letters included requests for the manufacturers to submit 510(k) applications so that FDA can evaluate the safety of the modification from an open to closed elevator wire channel.¹³⁴
- October 5: FDA orders postmarket surveillance studies. The manufacturers must answer whether their instructions are sufficient to ensure user adherence, the percent of scopes that remain contaminated after proper reprocessing, and the factors that contribute to contamination and what is needed to fully decontaminate the device.¹³⁵
- November 13: FDA issues a mandatory recall of Custom Ultrasonics AERs. FDA warned that Custom Ultrasonics AERs may not reliably clean devices and recommended that the hospitals and health facilities using about 2,800 Custom Ultrasonics machines move as quickly as possible to a different manufacturer's AERs.¹³⁶
- **December 31: FDA issues draft "emerging signals" guidance.** FDA's new guidance explains the agency will now notify the public when it learns about potentially serious device issues rather than wait until the agency has reached a conclusion about a problem or formed recommendations.¹³⁷

While FDA has taken a number of actions to address the outbreaks in 2015, the inability to access information about adverse events independently from hospitals and manufacturers, and the inability to query data in electronic health records and claims data, stymied FDA's investigation and response to the spreading superbug infections and other dangerous illnesses.

Overall, FDA had major gaps in information, or delays in receiving information, which led to an unacceptably slow response to the spread of deadly infections in ERCP patients. While some of the responsibility for this failure lies with the agency for losing a key adverse event report and missing relevant international adverse event reports, without a more robust surveillance system independent from the reporting of manufacturers and hospitals, it is likely that the same gaps and delays will occur in other device related investigations.

FDA Needs a More Robust Device Safety Surveillance System

A passive device surveillance system is ineffective even when manufacturers and hospitals self-report information about device safety to FDA.

Even if device manufacturers and hospitals had worked to fulfill their regulatory obligations and provide FDA with the information they knew about device issues as rapidly and completely as

possible, FDA's passive device surveillance system probably would have still taken an unacceptably long time to identify the extent of the device issues. Assuming an MDR is filed and contains relevant information, staff reviewers can assess the seriousness of a particular incident, but are unlikely to make connections or see patterns because MDRs are not linked to the reports of similar devices from the same or other manufacturers with the same type of adverse event. Even in the unlikely event that a staff member sees a sufficient number of reports related to particular device to notice a pattern, FDA reviewers lack a denominator of the total number of times a device is used, and accordingly, have no way of assessing how frequent or serious issues are relative to how often a device is used. If a reviewer sees ten MDRs reporting a device failure, it is almost impossible to know if that is ten out of 100 procedures, ten out of 10,000 procedures, or ten out of one million.

The current system provides no ability to run data analytics to help identify patterns or to alert FDA to unusual types of reports. The system as it is currently designed allows FDA only to query the passive database to pull up all the information it has about a specific device. This is only useful, however, once FDA suspects there is a problem and specifically runs a search related to that issue. Even so, FDA queries do not always pull up all the relevant information. Spelling mistakes and differences in the way that devices are named make searches difficult, and prior to February 2014, FDA relied on paper rather than electronic submissions.¹³⁸ Occasionally, as in the case of the initial Olympus UPMC MDR, paper adverse event reports received by the agency have been lost.

In contrast to the outdated and ineffective post-market monitoring system for devices, FDA has moved towards a more modern and effective system for overseeing the postmarket safety and effectiveness of drugs. The Food and Drug Amendments Act of 2007 (FDAAA) required FDA to establish a surveillance system that uses electronic health care data to monitor drugs using the unique product identifier known as an NDC, which is also included on all pharmacy insurance claims and on Medicaid claims for outpatient drugs prescriptions.¹³⁹ In 2009, FDA began to leverage the data provided by NDCs through the "Sentinel" initiative, which queries multiple health care data sources, including electronic health records and insurance claims information, to make links between patient outcomes and specific drugs.¹⁴⁰ The NDCs provide the key to making that link.

A system like Sentinel for devices is critical for two primary reasons. First, it does not rely exclusively on hospitals or manufacturers to report adverse events against weighty competing interests, but rather pulls information directly from databases that contain real-time information from insurance claims and other data that tracks patient care.¹⁴¹ This reduces the reliance on hospitals and manufacturers to self-report which, as this investigation has revealed, can happen months or even years after the fact and often lack important information. Second, Sentinel provides FDA with a "denominator" so that FDA can understand the number of adverse incidents reported in the context of the total number of patients treated.

Although it is not yet fully developed, a pilot "mini-Sentinel" has already substantially improved FDA's postmarket surveillance of drugs. For example, after being alerted to cases of serious intestinal issues linked to the blood pressure drug Olmesartan, FDA analyzed the data in Sentinel to assess whether such issues were limited to the particular drug or whether all similar drugs caused intestinal problems.¹⁴² FDA was able to determine that only Olmesartan was linked to higher rates of celiac disease, and therefore notify patients of particular issues with a specific drug rather than

an entire class of drugs.¹⁴³ Similarly, after receiving a large number of reports of fatal bleeding associated with the drug Dabigatran to treat abnormal heart rhythms, FDA used the information in Sentinel to assess whether the rates of bleeding in Dabigatran patients were in fact higher than the rates in the clinical trial.¹⁴⁴ FDA found that the rates were not significantly different from the results of the trial or from other similar drugs on the market, which ensured that doctors knew they could safely continue prescribing Dabigatran.¹⁴⁵

A Sentinel-like system can also assist FDA and manufacturers to complete postmarket surveillance studies of the safety or effectiveness of a device required under section 522 of the Food, Drug, and Cosmetic Act (section 522 postmarket surveillance studies). Currently, there are few incentives for clinicians and patients to participate in the studies, and without UDI codes in claims data, it is difficult for device manufacturers to find ways to link use of their devices to patient outcomes.¹⁴⁶ A Sentinel system would help manufacturers to run more accurate studies quickly to answer lingering questions around the safety of duodenoscope and AER design. Moreover, a Sentinel system would allow FDA to run its own queries and investigations without relying on manufacturers, who have few incentives to complete the studies quickly.

Currently FDA cannot use Sentinel or similar system to perform surveillance on devices because there is no similar way to track specific devices across different health claims databases. The Food and Drug Administration Amendments Act of 2007 required FDA to issue regulations to create a UDI system for medical devices.¹⁴⁷ Like the NDCs for drugs, UDIs will be placed on medical device labels and packages. FDA issued the final rule in September of 2013 which phases in the UDI requirements over time starting in September 2014 and ending in September of 2020.¹⁴⁸

UDIs will be required to be included on MDR reports, which should make it easier for FDA to query its system to identify reports linked to particular devices.¹⁴⁹ The UDIs, however, unlike NDCs, are not currently included on insurance claims.¹⁵⁰

A system like Sentinel for surveillance of devices could have prevented life-threatening infections worldwide.

In September 2013, when FDA first started investigating the design of duodenoscopes, outbreaks of CRE potentially linked to closed-channel devices had occurred at Thomas Jefferson Hospital, Virginia Mason, Carolinas Medical Center, and Froedtert Hospital but had not yet been reported to federal regulators by device manufacturers or hospitals. If FDA had access to UDIs in insurance claims, it is possible that the agency could have identified those outbreaks for itself at the beginning of its investigation and potentially moved faster to understand that the design of duodenoscopes makes them difficult or impossible to reliably clean, developed consensus internally about the source of the problems, and more promptly taken action to warn patients and hospitals.

Instead, after learning about the reprocessing problems at Advocate Lutheran from CDC, FDA

took more than 17 months to issue its first safety alert to hospitals and almost two years to provide hospitals with additional measures to supplement their reprocessing of duodenoscopes. In the intervening months, at least 68 patients in the United States and 82 patients worldwide were

68 patient infections in the United States may have been prevented if hospitals had been alerted by FDA earlier to reprocessing difficulties.

infected with superbug and other antibiotic-resistant bacteria. Those infections, along with other infections that likely occurred but were never identified, could possibly have been prevented if

hospitals been aware of the reprocessing difficulties known to FDA a year and a half before its first safety warning about the devices.

In the case of duodenoscopes, FDA was overly cautious and waited to alert the public and hospitals to the risks posed by duodenoscopes until the agency had finished its investigation and developed recommendations for supplemental reprocessing procedures. FDA's release of draft guidance on December 31, 2015, which explains that the agency will now notify the public about emerging serious device issues more quickly, is a positive step that will allow the agency, the public, and hospitals to take action sooner when new device issues arise.

The inability to access adequate information about adverse events independently from hospitals and manufacturers, and the inability to gather information about devices from insurance claims data, stymied FDA's investigation and expedient attention and response to the spreading antibioticresistant infections and other dangerous illness.

Overall, major gaps or delays in receiving information led to an unacceptably slow response from the FDA to the spread of deadly infections in ERCP patients. Without a more robust surveillance system independent from the self-interested reporting of manufacturers and hospitals, it is likely the same gaps and delays will continue to occur with other device related investigations.

Conclusion

Senator Murray's staff investigation demonstrates that duodenoscopes spread life-threatening, antibiotic-resistant and superbug infections among patients in a number of hospitals throughout the United States and Europe in 2013 and 2014. These outbreaks occurred despite the fact that the manufacturer of 85 percent of the duodenoscopes used in the United States, Olympus, was aware by early 2012 that its closed-channel duodenoscope could harbor dangerous bacteria even after repeated and careful cleaning according to instructions.

Multiple hospitals were also aware that duodenoscopes were linked to antibiotic-resistant and superbug infections in ERCP patients. Yet none of the three manufacturers of duodenoscopes sold in the United States – Olympus, Fujifilm, and Pentax – and only one hospital, ever alerted CDC to the infections. The device manufacturers and most hospitals also largely failed to meet their legal obligations to provide complete and timely information about serious patient infections and deaths to manufacturers and/or FDA.

The duodenoscope manufacturers and Custom Ultrasonics, the manufacturer of an AER used to clean duodenoscopes between uses, failed at every level to meet basic expectations of transparency and openness and to actively engage with FDA to address contamination issues. This disregard for the spirit, and sometimes the letter, of the law resulted in potentially preventable serious and potentially fatal illnesses in hospitals around the world.

As a result, when FDA first became aware of the outbreak at Advocate Lutheran, the agency lacked critical pieces of information that would have better allowed its staff to understand the frequency with which infections were occurring and that duodenoscopes could remain contaminated even after reprocessing instructions were followed correctly. Throughout 2014, FDA investigated the infections but did not issue any safety communications to inform hospitals of the risk posed by even duodenoscopes that are reprocessed according to manufacturers' instructions and reprocessed with cleared AERs. While FDA took significant steps in 2015 to alert hospitals to the risks of

contaminated duodenoscopes, study supplemental cleaning procedures to help ensure the devices are safe for reuse, require new data from manufacturers to prove that their cleaning instructions work, recall about 2,800 AERs, and require manufacturers to conduct postmarket surveillance studies, these steps ought to have been taken months or even a year sooner.

This investigation clearly demonstrates the inability of FDA's current device surveillance system to accurately identify the extent of device problems when they occur, which poses an unacceptable risk to patients. In contrast to the surveillance system for drugs, which increasingly uses unique identifiers to track drug performance through electronic health records and insurance claims, the

In contrast to the surveillance system for drugs, the device surveillance system relies almost exclusively on the selfreporting of manufacturers and hospitals. device surveillance system continues to rely almost exclusively on the self-reporting and self-regulation of manufacturers and hospitals. Had FDA been able to utilize a similar surveillance system to pull information about ERCP patient outcomes from insurance claims and health records data, it is possible that as early as September 2013 the agency would have understood the extent of the threat posed by contaminated closedchannel duodenoscopes. FDA would have been able to

identify outbreaks in far more facilities than were identified at the time and link those infections to particular models of duodenoscopes and AERs. As a result, the agency could have completed its investigation sooner and more quickly issued safety alerts to hospitals.

The failure of FDA's device surveillance system to rapidly identify and respond to duodenoscoperelated superbug and antibiotic-resistant infections serves as just one example of the fallacy of a system that is primarily reliant on hospitals and device manufacturers to self-report information to FDA. This investigation has shown that the expectation for device manufacturers and hospitals, despite strong competing priorities, to file 501(k) applications for device modifications, adequately validate devices before they are marketed, and quickly and accurately report potential devicerelated injuries and deaths as required by the current system, is ineffective.

The systematic failures identified in this report are, unfortunately, likely not confined solely to duodenoscopes. Without improved communication for each stakeholder from hospitals to manufacturers to state and local health departments, to FDA and CDC, and without a comprehensive postmarket device surveillance system that supplements self-reporting from hospitals and manufacturers, future device-related safety issues are likely to go undetected for far too long and with life-threatening consequences.

Recommendations

In order to address the issues raised by this investigation, the HELP Committee minority staff recommends the following legislative and regulatory changes:

Recommendation #1: Congress should require and promote that unique device identifiers (UDIs) be included in insurance claims, electronic health records, and device registries.

The investigation demonstrates that FDA's reliance on self-reporting of adverse events by manufacturers and hospitals is unworkable and outdated, particularly when contrasted with the active postmarket surveillance system for drugs. The widespread inclusion of UDIs in medical

data including claims data, electronic health records, and registries, is an absolutely essential piece of any fully functional, high-quality device surveillance system. Without widespread adoption of UDIs in claims and electronic health data, FDA is severely hampered in its ability to move forward to implement an improved device surveillance system. Congress should require that claims data include the UDI number associated with medical devices used in procedures in order to ensure FDA is not caught in the dark when the next medical device is linked to serious illness, injury, or death.

Recommendation #2: FDA should evaluate whether modifications to the design of closedchannel duodenoscope are necessary to prevent the spread of infection, and if so, require manufacturers to rapidly implement any repairs through a phased recall to ensure that devices used by hospitals are safe for reuse.

This investigation has suggested that closed-channel duodenoscopes may spread infection between uses even when manufacturers' instructions are followed correctly and an effective AER is used. At least three independent evaluators have found that potential design flaws with the Olympus closed-channel duodenoscope prevent hospitals from reliably cleaning the devices between procedures. FDA should thoroughly evaluate the design of closed-channel duodenoscopes and consider immediate implementation of a phased recall to make any repairs or modifications necessary to ensure effective reprocessing.

Recommendation #3: FDA should update its guidance to clarify when manufacturers are required to submit a notification to FDA for 510(k) clearance before marketing modified devices.

In 2011, after becoming concerned about the number of manufacturers that failed to submit a notification to FDA for 510(k) clearance to account for substantial device modifications, FDA promulgated new draft guidance to clarify the existing 1997 document, to update the instructions, and to accommodate new technological advances. That guidance was subsequently withdrawn at the instruction of Congress in the Food Drug Administration Safety and Innovation Act (FDASIA) of 2012. The investigation provides renewed evidence of the need for updated guidance for device modifications.

Consistent with FDASIA, FDA should issue updated guidance that clarifies important terms that may confuse manufacturers regarding whether a 510(k) clearance is required, and that makes clear that manufacturers should verify and validate any determinations that safety and effectiveness are not impacted by a device modification.

Recommendation #4: FDA should move faster to provide information to health care providers when the agency becomes aware of information suggesting that patient safety might be compromised by a medical device.

A key finding of the investigation is that it took FDA almost 18 months from the time they learned of duodenoscope-linked infections to issue a safety communication alerting hospitals and the public to the risk posed by closed-channel duodenoscopes. Had FDA promptly notified hospitals earlier that there were potential safety issues with the reprocessing of closed-channel duodenoscopes, additional cleaning measure could have been adopted more quickly and issues with AER machines may have been identified more rapidly. Overall, earlier communication might

have prevented dozens of life-threatening infections including some that have never been identified.

The HELP Committee minority staff are pleased to note that on December 31 2015, FDA issued draft guidance to update the agency's procedures for notifying the public about potential device safety issues.¹⁵¹ Rather than wait until the agency has finishes an investigation and reaches a conclusion, FDA will now alert the public about to emerging safety concerns when the agency receives new information about serious or widespread public health issues.

Recommendation #5: FDA should have clear authority to deny a 510(k) submission based upon insufficient reprocessing validation data.

The investigation conclusively demonstrates that relying on reusable device manufacturers to attest that their reprocessing instructions have been sufficiently tested and will work reliably in real-world conditions is insufficient. FDA guidance issued in March 2105, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling guidance for Industry and Food and Drug Administration Staff," provides additional clarity that reprocessing data should be included with 510(k) submissions for some reusable devices. In order to ensure that manufacturers submit all the requisite validation data when marketing a new or modified device, Congress should clarify in statute FDA's authority to consider a 510(k) submission incomplete and deny marketing clearance if a reusable device manufacturer fails to provide validation data with the 510(k) submission.

Recommendation #6: Compliance with MDR reporting requirements should be a Condition of Participation in Medicare.

The investigation demonstrates that hospitals that performed exemplary public health work to identify and halt duodenoscope-linked antibiotic-resistant infections often failed to share that information with device manufacturers and to collaborate effectively with federal regulators. Hospitals that wish to participate in Medicare must meet certain conditions of participation specified and laid out in statute and regulation, including certain requirements for infection control and medical records services. In addition to enforcement efforts by FDA, Centers for Medicare and Medicaid Services should require that compliance with relevant medical device reporting requirements be included as a condition of participation in Medicare to ensure that state survey agencies and accrediting bodies such as the Joint Commission on Hospital Accreditation specifically examine whether hospitals are filing timely required medical device reports with hospitals or FDA.

Recommendation #7: Congress should fully fund a National Medical Device Evaluation System (NMEDS).

Widespread adoption of UDIs is an important step but is just one of many parts of a complete and robust device evaluation system. FDA must also facilitate a coordinating center to ensure interoperability between data sources and a governance structure to operate the system. Congress should provide sufficient funds for the agency to move towards these goals as rapidly as possible.

¹ Kristen Wnedorf, et.al, "Endoscopic Retrograde Cholangiopancreatography-Associated AmpC *Escherichia coli* Outbreak," Infection Control & Hospital Epidemiology, (March 30, 2015).

³ FDA, Effective Reprocessing of Endoscopes used in Endoscopic Retrograde Cholangiopancreatography (ERCP) Procedures, Executive Summary 14 (2015),

www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/UCM445592.pdf [hereinafter FDA Executive Summary].

⁴ Press Release, CDC, Action Needed Now to Halt Spread of Deadly Bacteria (2013), www.cdc.gov/media/releases/2013/p0305_deadly_bacteria.html.

⁵ Documents show discrepancies in the number of patients reported and the date of the infections. An additional five patients may have been infected with a multidrug-resistant infection after ERCP procedures at UMPC in summer and fall 2013 that were not reported to FDA.

⁶ Only six of these infections were linked to an Olympus duodenoscope. The remaining infections were linked to an unknown manufacturer's device.

⁷ FDA Executive Summary at 14.

⁸ Id. at 9.

⁹ *Id.* at 24; Letter from Keiichi Nagata, Division President, FUJIFILM Medical Systems USA, to Senator Patty Murray (June 19, 2015) (on file with the HELP Committee).

¹⁰ FDA Executive Summary at 24-25.

¹¹ FDA Executive Summary at 17-18.

¹² FDA, Center for Devices and Radiological Health, Reprocessing Medical Devices in Health Care Settings:

Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff 5-6 (March 7, 2015),

www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf. ¹³ *Id.*

¹⁴ *Id.* at 10.

¹⁵ FDA Executive Summary at 32-40.

¹⁶ FDA, "Classify Your Medical Device,"

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=876.1500.

¹⁷ 21 C.F.R. § 876.1500.

¹⁸ A device is substantially equivalent to another device if it (1) has the same intended use and the same technological characteristics, or (2) has the same intended use but with different technological characteristics that (a) do not raise new questions of safety and effectiveness and (b) demonstrate that it is at least as safe and effective as the legally marketed device. *See* FDA, Premarket Notification 510(k), "What is Substantial Equivalence?", www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/Pr emarketNotification510k/#se.

¹⁹ See 21 C.F.R § 807.

²⁰ See FDA, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff (March 17, 2015),

www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf.

²¹ Id.; 21 C.F.R. 820.75.

²² See FDA, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff (March 17, 2015),

www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM253010.pdf.

²³ 21 C.F.R. Section 803.50(a).

²⁴ 21 C.F.R. Section 803.30(a).

²⁵ FDA, "MedSun: Medical Product Safety Network,"

www.fda.gov/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/default.htm?source=govdelivery.

 $^{^{2}}$ Id.

²⁶ FDA Executive Summary at 11.

²⁷ As of Aug. 13, 2015, manufacturers and importers have been required to submit all MDRS electronically which should address some of these issues. (Medical Device Reporting: Electronic Submission Requirements, 79 Fed. Reg. 8832 – 8855).

²⁸ FDA, Draft Guidance for Industry and Food and Drug Administration Staff - Postmarket Surveillance Under Section 522 of the Federal Food, Drug and Cosmetic Act (Aug. 16, 2011), www.fda.gov/RegulatoryInformation/Guidances/ucm268064.htm.

²⁹ The Brookings Institution, "Strengthening Patient Care: Building an Effective National Medical Device Surveillance System," 12 (Feb. 2015), www.brookings.edu/~/media/research/files/papers/2015/02/23-medicaldevice-policy-surveillance/med-device-report-web.pdf

³⁰ *Id*.

³¹ Josh Rising, Ian Reynolds, and Art Sedrakyan, Pew Charitable Trusts, "Delays and Difficulties in Assessing Metal-on-Metal Hip Implants" (July 6, 2012), www.pewtrusts.org/en/about/news-room/opinion/2012/07/16/delays-and-difficulties-in-assessing-metalonmetal-hip-implants.

³² FDA, "FDA's Sentinel Initiative- Background," www.fda.gov/Safety/FDAsSentinelInitiative/ucm149340.htm.

³³ 21 U.S.C. § 360(i); Unique Device Identification System 78 Fed. Reg. 58786 – 58828.

³⁴ See FDA Executive Summary at 9.

³⁵ *Id*.at 25-27. The closed-channel duodenoscope models include the Olympus TJF-Q180V, the Fujifilm ED-530XT, and the Pentax ED-3490TK and ED-3670TK.

³⁶ MDR 8010047-2012-00157.

³⁷ Dr. Ir. Arjo Loeve, Delft University of Technology, "Investigation Olympus TJF-Q180V scope: Following detected contamination after cleaning and disinfection" (May 15, 2012) [hereinafter Delft report].

³⁸ Telephone conversation with Dr. Arjo Loeve (October 2, 2015).

³⁹ Delft report at 11.

⁴⁰ *Id.* at 23-24.

⁴¹ *Id.* at 23.

⁴² *Id*.

⁴³ *Id.* at 23-24.

⁴⁴ Delft report at 23-24.

 45 *Id*.

⁴⁶ Id.

⁴⁷ A. Bruijn, A. Drogelen, National Institute for Public Health and the Environment Ministry of Health, Welfare, and Sport, "Disinfection of Olympus TFJ-Q180V ERCP endoscope" (July 30, 2013) [hereinafter RIVM report].

⁴⁸ *Id*. at 1.

⁴⁹ *Id.* at p. 6.

⁵⁰ See, e.g., MDR 8010047-2015-00216.

⁵¹ Telephone conversation with staff at UPMC (October 29, 2015).

⁵² MDR 8010047-2012-00481.

⁵³ Letter from Scott Lucas, Program Manager at ECRI Institute to William Schaffner, Senior Associate Counsel at UPMC (December 26, 2012) (on file with the HELP Committee).

⁵⁴ MDR 8010047-2012-00481; Memorandum from Mary Ann Drosnock to David Barlow, Simon Nguyen, Laura Storms-Tyler, and Mia Zhang (December 14, 2012) (on file with the HELP Committee); Letter from Scott Lucas, Program Manager at ECRI Institute to William Schaffner, Senior Associate Counsel at UPMC (December 26, 2012) (on file with the HELP Committee).

⁵⁵ Letter from Scott Lucas, Program Manager at ECRI Institute to William Schaffner, Senior Associate Counsel at UPMC (December 26, 2012) (on file with the HELP Committee).

⁵⁶ Telephone conversation with staff at UPMC (October 29, 2015).

⁵⁷ Olympus has provided documentation that confirms the MDR was sent to FDA.

⁵⁸ Biotech Germande study 2128.Oly.2012 (: 08-Jan-2013) (on file with the HELP Committee).

⁵⁹ Biotech Germande study 2231.Oly.2013 (July 2, 2014) (on file with the HELP Committee).

⁶⁰ Bonn University studies on file with the HELP Committee. It is unclear whether the scope evaluated by Bonn University was linked to a particular outbreak

⁶¹ Letter from Olympus to customers, "Important Safety Advice" (Jan. 2013),

www.swissmedic.ch/recalllists_dl/07207/Vk_20130123_15-e1.pdf (emphasis added).

⁶² These three outbreaks are: Erasmus Medical Center in the Netherlands, UPMC in the United States, and Clinique de Bercy in France.

⁶³ Letter from Olympus to customers, "URGENT: Field Safety Corrective Action" (2014, www.swissmedic.ch/recalllists dl/10220/Vk 20140729 02-e1.pdf (emphasis added).

⁶⁴ These ten outbreaks are: Erasmus Medical Center, UPMC, Clinique de Bercy (two outbreaks), Evangelisches Waldkrankenhaus Spandu, Hartford Hospital, Froedtert Hospital, NYP/Weill Cornell Medical Center, UMass Memorial Hospital, and Charite-Universitatsmedizin,

⁶⁵ See 21 C.F.R 807.81(a)(3).

⁶⁶ FDA, "Deciding When to Submit a 510(k) for a Change to an Existing Device. Memorandum # K97-1" (1997), www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm.

⁶⁷ Id

⁶⁸ Letter from LaShonda M. Long, Chief of Surveillance and Enforcement Branch I, to Laura Storms-Tyler, Vice President of Olympus Medical Systems Corporation, "It Has Come to Our Attention" (March 18, 2014), www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM436587.pdf.

69 See 21 C.F.R. § 820.30(g).

⁷⁰ See 21 C.F.R. 820.75; FDA Executive Summary at 30.

⁷¹ FDA, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Guidance for Industry and Food and Drug Administration Staff, 22-23 (2015),

www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf ⁷² RIVM report at p. 9.

⁷³ *Id.* at p. 4.

⁷⁴ *Id.* at ps. 7-8.

⁷⁵ In March 2015 FDA found that Olympus had validated updated reprocessing instructions. FDA, Safety Communication "Olympus Validates New Reprocessing Instructions for Model TJF-Q180V Duodenoscopes" (March 26, 2015), www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm439999.htm.

⁷⁶ FDA, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Guidance for Industry and Food and Drug Administration Staff (March 17, 2015),

www.fda.gov/downloads/medical devices/device regulation and guidance/guidance documents/ucm 253010.pdf

⁷⁷ Hospitals and other user facilities are required to report serious injuries linked to devices to manufacturers but are not required to report serious injuries to FDA.

⁷⁸ MDR 8010047-2012-000157 (understating the number of patients infected at Erasmus Medical Center).

⁷⁹ See, e.g., MDR 8010047-2013-00595 (Clinique de Bercy) ("improper reprocessing could not be ruled out as a contributory factor"); MDR 8020047-2013-00092 (Charite-Universitatsmedizin); MDR 8010047-2012-000452 (Clinique de Bercy).

⁸⁰ Letter from Jan B. Welch, Acting Director, Office of Compliance, FDA, to Akihiro Okubo, President, Olympus Medical Systems Corporation, "Warning Letter" (Aug. 12, 2015),

www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm458510.htm.

⁸¹ Letter from Keiichi Nagata, Division President FUJIFILM Medical Systems USA to Senator Patty Murray (June 19, 2015) (on file with the HELP Committee).

⁸² Letter from Anastacia M. Bilek, Director, Division of Premarket and Labeling Compliance, FDA, to Mr. Teiichi Goto, Corporate Vice President, Fujifilm Corporation, "It has come to our attention" (Aug. 12, 2015), www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM458552.pdf.

⁸³ Id.

⁸⁶ Id.

⁸⁷ Id.

⁸⁸ *Id.* (observation 3).

⁸⁹ Letter from Jan B. Welch, Acting Director, Office of Compliance, FDA to Mr. Hiroshi Suzuki, President and CEO, Hoya Corporation (PENTAX Life Care Division), Warning Letter (Aug 12, 2015), www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm458487.htm.

 90 Pentax instructs user facilities to use either an EtO/Carbon Dioxide 80:20 or 90:10 mixture when sterilizing a duodenoscope but the validation was performed with an EtO/HCFC 10:90 gas mixture – a different mixture from the gas included on the label. (*Id.*).

⁹¹ FDA, Safety Communication, "FUJIFILM Medical Systems, U.S.A., Inc. Validates Revised Reprocessing Instructions for Model ED-530XT Duodenoscopes" (Dec. 23, 2015),

www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm439999.htm

⁹² Letter from Jan B. Welch, Acting Director, Office of Compliance, FDA to Mr. Hiroshi Suzuki, President and CEO, Hoya Corporation (PENTAX Life Care Division), Warning Letter (Aug 12, 2015),

www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm458487.htm.

⁹³ Letter from Jan B. Welch, Acting Director, Office of Compliance, FDA to Mr. Teiichi Goto, Corporate Vice President, Fujifilm Corporation, Warning Letter (Aug. 12, 2015),

www.fda.gov/iceci/enforcementactions/warningletters/2015/ucm458453.htm.

⁹⁴ In November, 2014 Pentax reported patients at a hospital in Udine, Italy developed a Klebsiella pneumoniae infection after undergoing ERCP. MDR 9610877-2015-00046.

⁹⁵ Email from counsel to Pentax to HELP committee staff (October 28, 201) (on file with the HELP Committee).

⁹⁶ Letter from Counsel for Fujifilm to Senator Patty Murray (October 2, 2015) (on file with the HELP Committee).

⁹⁷ Press Release, FDA, "FDA orders recall under consent decree for all custom ultrasonics automated endoscope reprocessors" (Nov. 13, 2015), www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm472605.htm.

⁹⁸ Letter from Thomas D. Gardine, District Director, FDA, to Frank J. Weber, President & CEO, Custom Ultrasonics, Warning Letter (June 22, 2005),

/www.fda.gov/ICECI/EnforcementActions/WarningLetters/2005/ucm075455.htm.

⁹⁹ FDA, Safety Communication, "Custom Ultrasonics, Inc. Endoscope Washer/Disinfectors" (Feb. 27, 2007), www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm064361.htm.

¹⁰⁰ Telephone conversation with FDA (Dec.7, 2015).

¹⁰¹ Letter from Anne E. Johnson, Acting Director, Philadelphia District, Office of Regulatory Compliance and Capt. Sean Boyd, Acting Director of Compliance, FDA, to Alicia Nakonetschny, President and CEO, Custom Ultrasonics (Nov. 12, 2015),

www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHFOIAElec tronicReadingRoom/UCM472567.pdf.

 102 *Id*.

103 21 C.F.R. § 803.30.

 104 *Id*.

¹⁰⁵ Committee staff were unable to obtain information from Carolinas Medical Center in Charlotte North Carolina after repeated inquiries.

¹⁰⁶ For state reporting requirements *see* Association for Professionals in Infection Control and Epidemiology, "Summary of State CRE Reporting Requirements," www.apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/CRE_ReportingRequirements_Final.pdf.

¹⁰⁷ Telephone conversation with staff at Virginia Mason (October 29, 2015).

¹⁰⁸ Id.

⁸⁴ Letter from Anastacia M. Bilek, Director, Division of Premarket and Labeling Compliance, to Mr. Hiroshi Suzuki, President and CEO, Hoya Corporation (PENTAX Life Care Division), "It has come to our attention" (Aug. 12, 2015), www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM458554.pdf.

⁸⁵ FDA, Form 483, Observation 1, inspection of a Fujifilm Facility in Ashigarakami Gun, Japan (April 23-May 01, 2015).

¹⁰⁹ MDR 2951238-2014-00644.

¹¹⁰ MDR 2518897-2015-00329.

¹¹¹ 21 C.F.R. § 803.30(a)(1).

¹¹² Letter from Thomas Kraus, Associate Commissioner for Legislation, FDA, to Senator Patty Murray (May 14, 2015) (on file with the HELP Committee).

¹¹³ MedWatch 5029305.

¹¹⁴ MedWatch 5032234.

¹¹⁵ Telephone Call with staff at Virginia Mason (October 29, 2015).

¹¹⁶ There is no federal requirement that user facilities report all antibiotic-resistant infections, or even all CRE outbreaks, to the CDC. Instead, hospitals voluntarily report hospital-acquired infections to the National Healthcare Safety Network (NHSN) or the Gram-Negative Bacilli Surveillance Initiative (MuGSI). MuGSI was created specifically to track CRE infections but includes data from only eight surveillance sites in Colorado, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee. The CDC has been unable to confirm that any of the identified outbreaks prior to fall 2013 were reported to any of their databases. *See* CDC, "What is NHSN?" (last accessed Nov. 30, 2015), www.cdc.gov/nhsn/about-nhsn/index.html; CDC, "Technical Information-Multi-Site Gram-Negative Bacilli Surveillance Initiative (MuGSI)" (last accessed Nov. 30, 2015), www.cdc.gov/hai/eip/mugsi_techinfo.html.

¹¹⁷ 21 C.F.R. § 803.30 (emphasis added).

¹¹⁸ FDA Executive Summary at 11.

¹¹⁹ Telephone conversation with staff at Advocate Lutheran (November 19, 2015).

 120 Id.

¹²¹ MDR 8010047-2012-00157. There were actually at least 30 patients infected.

¹²² MDR 8010047-2012-00481. Olympus has provided supporting documentation that the original report was sent to FDA, but it does not appear that it was ever entered into FDA's adverse event reporting database and FDA experts conducting the investigation do not appear to have seen this MDR until a later time.

¹²³ MDR 2951238-2013-00031.

¹²⁴ MDR 8010047-2012-00452.

¹²⁵ MDR 8010047-2013-00092.

¹²⁶ MDR 8010047-2013-00176.

¹²⁷ MW 5031083.

¹²⁸ Letter from Senator Patty Murray to Margaret Hamburg, FDA Commissioner (February 3, 2014), www.murray.senate.gov/public/_cache/files/096ecf61-0004-4076-b2e0-8fd4f1a25e78/020315-virginia-mason-letter.pdf.

¹²⁹ FDA, Safety Communication, "Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning" (February 19, 2015 updated March 4, 2015), www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm434871.htm.

¹³⁰ CDC, "Interim Duodenoscope Surveillance Protocol," www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html.

¹³¹ FDA, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Guidance for Industry and Food and Drug Administration Staff (March 17, 2015),

www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf

¹³² FDA Executive Summary. Virginia Mason has extensively studied the culture and quarantine protocol at its facility, and continues to find about two percent of its duodenoscopes remain contaminated after reprocessing even using Olympus's updated cleaning instructions.

¹³³ FDA, Safety Communication, "Supplemental Measures to Enhance Duodenoscope Reprocessing" (Aug. 4, 2015), www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm454766.htm.

¹³⁴ Letter from Jan B. Welch, Acting Director, Office of Compliance, FDA to Mr. Teiichi Goto, Corporate Vice President, Fujifilm Corporation, Warning Letter (Aug. 12, 2015),

www.fda.gov/iceci/enforcementactions/warningletters/2015/ucm458453.htm; Letter from Jan B. Welch, Acting

Director, Office of Compliance, FDA to Mr. Hiroshi Suzuki, President and CEO, Hoya Corporation (PENTAX Life Care Division), Warning Letter (Aug 12, 2015),

www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm458487.htm; Letter from Jan B. Welch, Acting Director, Office of Compliance, FDA, to Akihiro Okubo, President, Olympus Medical Systems Corporation, "Warning Letter" (Aug. 12, 2015),

www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm458510.htm.

¹³⁵ Press Release, FDA, "FDA orders duodenoscope manufacturers to conduct postmarket surveillance studies in health care facilities" (Oct. 5, 2015), www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm465639.htm.

¹³⁶ Press Release, FDA, "FDA orders recall under consent decree for all custom ultrasonics automated endoscope reprocessors, (Nov. 13, 2015), www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm472605.htm.

¹³⁷ Public Notification of Emerging Postmarket Medical Device Signals ("Emerging Signals"); Draft Guidance, 80 Fed. Reg. 81829 – 81830.

¹³⁸ FDA published a final rule on February 13, 2014 requiring manufacturers and importers to submit electronic MDRs in a reviewable format, but allowed for hardcopy submissions until August 13, 2015. User facilities are allowed to continue submitting hardcopy MDRs but are given the option of e-filing reports as well. Medical Device Reporting: Electronic Submission Requirements, 79 Fed. Reg. 8832 – 8855.

¹³⁹ See Deficit Reduction Act of 2005 § 6002; 42 U.S.C. § 1396r-8(a); 21 U.S.C. § 360; Drug Listing Act of 1972, §§ 3, 4.

¹⁴⁰ FDA, "Sentinel Program Interim Assessment (FY 15)" (Sept. 24, 2015),

www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM464043.pdf.

¹⁴¹ *Id.* at 12.

¹⁴² *Id.* at 23-24.

¹⁴³ *Id.* at 23-24.

¹⁴⁴ *Id.* at 21-22.

¹⁴⁵ *Id*.

¹⁴⁶ See Brookings Institution, Strengthening Patient Care: Building an Effective National Medical Device Surveillance System (Feb. 2015), www.brookings.edu/~/media/research/files/papers/2015/02/23-medical-device-policy-surveillance/med-device-report-web.pdf.

¹⁴⁷ Food and Drug Administration Amendments Act of 2007 § 226; 21 U.S.C. § 360i(f).

¹⁴⁸ Unique Device Identification System 78 Fed. Reg. 58786 – 58828.

¹⁴⁹ "Medical Device Reporting" 21 C.F.R. §§ 803.32-33, 803.42, 803.52.

¹⁵⁰ The Office of the National Coordinator for Health Information Technology's "2015 Edition Health Information Technology Certification Criteria" rule made progress towards enabling access to and sharing of unique device identifier information. This rule requires that federally-certified health information technology allow a user to access a list of UDIs for a patient's implantable devices and share it with other authorized users. 80 Fed. Reg. 62601.

Appendix I: Letters

The following are reproductions of the letters Senator Murray sent to Olympus, Pentax, Fujifilm, and FDA.

LAMAR ALEXANDER, TENNESSEE, CHAIRMAN

MICHAEL B. ENZI, WYOMING RICHARD BURR, NORTH CAROLINA JOHNNY ISAKSON, GEORGIA RAND PAUL, KENTUCKY SUSAN M. COLLINS, MAINE LISA MURKOWSKI, ALASKA MARK KIRK, ILLINOIS TIM SCOTT, SOUTH CAROLINA ORRIN HATCH, UTAH PAT ROBERTS, KANSAS BILL CASSIDY, M.D., LOUISIANA PATTY MURRAY, WASHINGTON BARBARA A. MIKULSKI, MARYLAND BERNARD SANDERS (I), VERMONT ROBERT P. CASEY, JR., PENNSYLVANIA AL FRANKEN, MINNESOTA MICHAEL F. BENNET, COLORADO SHELDON WHITEHOUSE, RHODE ISLAND TAMMY BALDWIN, WISCONSIN CHRISTOPHER S. MURPHY, CONNECTICUT ELIZABETH WARREN, MASSACHUSETTS

DAVID P. CLEARY, STAFF DIRECTOR EVAN SCHATZ, DEMOCRATIC STAFF DIRECTOR

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United States Senate

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS WASHINGTON, DC 20510–6300

June 8, 2015

Karl Watanabe President and Chief Financial Officer Olympus Corporation of the Americas 3500 Corporate Parkway, P.O. Box 610 Center Valley, PA 18034-0610

Dear Mr. Watanabe:

As questions continue to arise regarding your company's actions to adequately protect patients treated with your duodenoscopes, I write to seek more information and express my serious and growing concern. As you are aware, between late 2012 and January 2014, Virginia Mason hospital in Seattle, Washington experienced an outbreak of deadly carbapenem-resistant Enterobacteriaceae (CRE) infections which were subsequently traced to duodenoscopes manufactured by Olympus. In all, 32 individuals were infected with CRE, an additional 7 people developed a separate *E coli* infection, and 18 of those who developed infections later died.¹

In addition, multiple cases of CRE infections traced back to Olympus duodenoscopes have now been confirmed at two other hospitals in 2014, as well as a series of CRE infections involving an Olympus duodenoscope in Florida in 2009. In all, the Food and Drug Administration (FDA) confirmed at the recently convened Advisory Committee Meeting of the <u>Gastroenterology-Urology Devices Panel</u> that there have been at least nine hospital outbreaks of multidrug-resistant infections traced to duodenoscopes in the United States, and that six of those outbreaks are traceable to scopes manufactured by Olympus.² Olympus is reported to have told health care professionals in February that the company was aware of 95 complaints of infection in patients who had undergone procedures with TJF-Q180V, the "closed elevator" duodenoscope sold since 2010, without Olympus seeking FDA approval or clearance before marketing.³

Overall, FDA has informed me it received 139 separate reports of contamination or infection related medical device reports, or adverse event reports involving duodenoscopes between 2011 and 2014, including 69 reports affecting 135 patients in 2014 alone.⁴ Ninety-four percent of these reports were received directly from the manufacturers, which include Olympus (85 percent market share of duodenoscopes), Fujifilm, and Pentax Medical.⁵

⁵ Id.

¹ Many of the individuals who died suffered from serious illnesses and thus, those deaths may not be the direct result of the CRE infections.

² FDA Executive Summary, Meeting of the <u>Gastroenterology-Urology Devices Panel of the Medical Devices Advisory</u> <u>Committee</u>, pp.14-15.

³ Chad Terhune and Melody Petersen, "Scope maker Olympus faces scrutiny over patient deaths, infections" Los Angeles Times, March 1, 2015.

⁴ Response from Thomas A. Kraus, Associate Commissioner for Legislation, Food and Drug Administration to Senator Murray, May 15, 2015.

I have become increasingly concerned by the failure of Olympus to proactively warn patients and providers in the United States of the potential for infections. It is my understanding that in November of 2013, at the invitation of officials at Virginia Mason concerned about the CRE infections at the hospital, an endoscopy support specialist from Olympus spent two days at the hospital and validated that the hospital was properly cleaning Olympus duodenoscopes between uses. That review by Olympus staff demonstrated that "endoscope reprocessing procedures at [the hospital] were above the industry standard, and all technicians performed manual endoscope cleaning in a manner consistent with manufacturer guidelines."⁶ Olympus officials subsequently removed a number of the scopes in use at Virginia Mason for repair.

Thus, as early as November 2013, it appears that Olympus knew or should have known that even in cases where hospital staff were carefully executing Olympus' instructions for cleaning, duodenoscopes continued to be contaminated with CRE and other bacteria. Further, it strongly suggests that Olympus knew its current cleaning and reprocessing standards were insufficient, and that use of the company's duodenoscopes, particularly the TJF-Q180V model sold since 2010 and featuring a "closed elevator," were placing patients undergoing procedures at risk of multi-bacteria resistant infections. Moreover, although medical device manufacturers are required to file reports of possible safety risks within 30 days, press reports suggest that Olympus did not even file the required Medical Device Report with the FDA in connection with the Virginia Mason infections until August 2014.⁷ And as recently as February of this year, more than a year after the Virginia Mason CRE outbreak, I understand that the Olympus manager of infection control told a meeting of health care professionals that "endoscopes reprocessed properly pose virtually no risk of patient-borne or environmental organisms."⁸

This stands in marked contrast to the actions taken by Olympus in Europe. According to press reports, as early as January 2013, Olympus is reported to have issued "important safety advice" to European hospitals instructing staff to use a specific brush supplied by Olympus to clean duodenoscopes. This action is reported to have been taken following a series of infections at Erasmus University in Rotterdam in early 2012. Dr. Margreet Vos provided testimony at the recent FDA Advisory Committee meeting that in 2012 independent reviewers found bacteria present in reprocessed Olympus scopes.

Again in August 2014, Olympus is reported to have sent a second safety alert to European hospitals that asked hospital staff to sign and return an acknowledgement that the warning had been shared with staff. No such alert was sent in this country until February of this year, and the cleaning brushes apparently sent to European hospitals in early 2013 were not provided to U.S. hospitals until last month.

These facts build upon my existing concerns regarding Olympus' 2010 failure to seek clearance or approval from the FDA prior to marketing TJF-Q180V, the "closed elevator" duodenoscope at issue in a number of the infections. I find it very troubling that when Olympus

⁶ See Kristen A. Wendorf, Megan Kay, et al. "Endoscopic Retrograde Cholangiopancreatography-Associated AmpC *Escherichia coli* Outbreak" Infection Control & Hospital Epidemiology, May 2015 p. 8.

⁷ Peter Eisler, "Reports to Feds on deadly bacteria outbreaks arrived late" USA Today, April 15, 2015.

⁸ Chad Terhune and Melody Petersen, "Scope maker Olympus faces scrutiny over patient deaths, infections" Los Angeles Times, March 1, 2015.

became aware of increased reports of infections linked to the TJF-Q180V, the company appears not to have taken additional steps to alert health professionals and regulators in the United States to the risks this particular device posed. Moreover, when asked by the FDA in the spring of 2014 to provide the data that validated that Olympus duodenoscopes could be cleaned of bacteria within acceptable safety margins using recommended procedures, Olympus (as well as Fujifilm and Pentax Medical) was unable to do so through two rounds of testing.⁹ New cleaning guidance was finally approved by FDA in March 2015.

I find it similarly troubling that Olympus (as well as Fujifilm and Pentax Medical) declined to participate in the subsequently convened FDA Advisory Committee Meeting on "Effective Reprocessing of Endoscopes used in Endoscopic Retrograde Cholangiopancreatography (ERCP) Procedures," despite manufacturing 85 percent of the scopes used in these procedures. But at the same time, the company was apparently able to have representatives present at two large professional conferences in Washington, D.C. that same week.¹⁰ Just days before the FDA Advisory Panel meeting, Olympus announced that the company was reducing its expected earnings forecast for this year as a result of an ongoing investigation by the Department of Justice into potential violations of the Anti-Kickback Statute, and last week Olympus announced that it is under investigation by the United States Attorney for the District of New Jersey relating to the duodenoscope infections.¹¹

Even with enhanced cleaning procedures adopted earlier this year, these necessary and important devices must be handled with extreme care to help prevent infections. At the FDA panel meeting, two-thirds of hospitals reported that scope cultures were positive for organisms after reprocessing. While representatives of Virginia Mason explained that the hospital has established a protocol requiring that, after a duodenoscope has been thoroughly cleaned and reprocessed, it is cultured for bacteria, this process requires a 48-hour waiting period between uses of a scope, and has required the hospital to purchase additional scopes.¹² Yet the hospital believes it has little alternative to purchasing additional scopes given that they continue to experience a 3 percent contamination rate.¹³

I am committed to ensuring that the families impacted by these tragic outbreaks in Washington State and across the country get answers and accountability. In order to better understand the timeline of events and your company's response to reports of infections related to duodenoscopes manufactured by Olympus, including the TJF-160, TJF-Q180V-1 and TJF-Q180V-2, please provide the following information by June 19, 2015.

⁹ "FDA Moves to Ensure Scope Safety", Los Angeles Times, March 15, 2015; Information provided by Dr. Vos to the Advisory Committee panel indicated that Olympus failed to provide requested information regarding the efficacy of cleaning procedures to the Dutch National Institute of Public Health and the Environment.

¹⁰ Chad Terhune, "Scope maker defends device design" Los Angeles Times, May 19, 2015.

¹¹ Olympus News Release, Recognition of Extraordinary Loss Due to the Investigation by the U.S. Department of Justice Against Our Subsidiary and Notice of Difference Between Consolidated Earnings Forecast and Actual Results, May 8, 2015; Olympus Financial Results filing, Consolidated Financial Results for the Fiscal Year Ended March 31, 2015; Chad Terhune and Melody Petersen "Justice Department investigates scope maker Olympus over superbug outbreaks" Los Angeles Times, May 28, 2015.

¹² FDA Executive Summary, Meeting of the <u>Gastroenterology-Urology Devices Panel of the Medical Devices Advisory</u> <u>Committee</u> p. 15.

¹³ Kristen A. Wendorf, Megan Kay, et al. "Endoscopic Retrograde Cholangiopancreatography-Associated AmpC *Escherichia coli* Outbreak" Infection Control & Hospital Epidemiology, May 2015 p. 8.

- 1. Copies of all alerts, cleaning guidance, safety advice or warnings provided to any hospital or regulatory agency, foreign or domestic, mentioning any scope manufactured by Olympus used in Endoscopic Retrograde Cholangiopancreatography Procedures from 2005-2015.
- 2. Unredacted copies of all medical device reports or adverse event reports sent by Olympus to FDA regarding the TJF-Q180V-1 and TJF-Q180V-2 or any other scope used in Endoscopic Retrograde Cholangiopancreatography Procedures between 2005 and present.
- 3. Copies of all documents between 2010 and present that reference or refer to CRE or other infections and any endoscope, including any duodenoscope, manufactured by Olympus.

Sincerely,

Patty Munay

Senator Patty Murray Ranking Member, HELP Committee

cc: Senator Lamar Alexander, Chairman of the HELP Committee

LAMAR ALEXANDER, TENNESSEE, CHAIRMAN

MICHAEL B. ENZI, WYOMING RICHARD BURR, NORTH CAROLINA JOHNNY ISAKSON, GEORGIA RAND PAUL, KENTUCKY SUSAN M. COLLINS, MAINE LISA MURKOWSKI, ALASKA MARK KIRK, ILLINOIS TIM SCOTT, SOUTH CAROLINA ORRIN HATCH, UTAH PAT ROBERTS, KANSAS BILL CASSIDY, M.D., LOUISIANA PATTY MURRAY, WASHINGTON BARBARA A. MIKULSKI, MARYLAND BERNARD SANDERS (I), VERMONT ROBERT P. CASEY, JR., PENNSYLVANIA AL FRANKEN, MINNESOTA MICHAEL F. BENNET, COLORADO SHELDON WHITEHOUSE, RHODE ISLAND TAMMY BALDWIN, WISCONSIN CHRISTOPHER S. MURPHY, CONNECTICUT ELIZABETH WARREN, MASSACHUSETTS

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United States Senate

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS WASHINGTON, DC 20510–6300

June 8, 2015

Masataka Akiyama President and Chief Executive Officer Fujifilm Medical Systems USA, Inc. 419 West Avenue Stamford, CT 06902

Dear Mr. Akiyama:

As questions continue to arise regarding Fujifilm Medical Systems USA's (Fujifilm) actions to adequately protect patients treated with duodenoscopes, I write to seek more information and express my serious and growing concern. As you are likely aware, between late 2012 and January 2014 Virginia Mason hospital in Seattle, Washington experienced an outbreak of deadly carbapenem-resistant Enterobacteriaceae (CRE) infections which were subsequently traced to duodenoscopes manufactured by Olympus Corporation. In all, 32 individuals were infected with CRE, an additional 7 people developed a separate *E. coli* infection, and 18 of those who developed infections later died.¹

Multiple cases of CRE infections traced back to duodenoscopes have now been confirmed at other hospitals in 2014. In fact, the Food and Drug Administration (FDA) stated at the recently convened Advisory Committee Meeting of the <u>Gastroenterology-Urology Devices Panel</u> that there have been at least nine hospital outbreaks of multi-drug resistant infections traced to duodenoscopes in the United States, including one outbreak of CRE in 2014 traceable to scopes manufactured by Fujifilm.²

Overall, FDA has informed me that 139 separate reports of contamination or infectionrelated medical device reports, or adverse event reports involving duodenoscopes were received between 2011 and 2014, including 69 reports affecting 135 patients in 2014 alone.³ Ninety-four percent of these reports were received directly from the manufacturers, which include Olympus, Pentax Medical and your company.⁴

¹ Many of the individuals who died suffered from serious illnesses and thus, those deaths may not be the direct result of the CRE infections.

² FDA Executive Summary, Meeting of the <u>Gastroenterology-Urology Devices Panel of the Medical Devices Advisory</u> <u>Committee</u>, pp.14-15.

³ Response from Thomas A. Kraus, Associate Commissioner for Legislation, Food and Drug Administration to Senator Murray, May 15, 2015.

⁴ Id.

I have become increasingly concerned by the failure of the three manufacturers to proactively warn patients and providers of the potential for infections. By September 2013 the Center for Disease Control and Prevention (CDC) had notified the FDA of the possible connection between multi-resistant bacteria hospital infections and duodenoscopes even when reprocessed according to the manufacturer's instructions.⁵ At approximately the same time, in November of 2013, an Olympus endoscopy support specialist found that Virginia Mason, which was attempting to contain a CRE outbreak, was properly reprocessing duodenoscopes stating "endoscope reprocessing procedures at [the hospital] were above the industry standard, and all technicians performed manual endoscope cleaning in a manner consistent with manufacturer guidelines."⁶ Thus, it appears that duodenoscope manufacturers should have been aware by at least late 2013 of the very real risk of multi-drug resistant infection from procedures using duodenoscopes even when cleaned according to instructions provided by the manufacturers.

While it has been reported that Fujifilm submitted a timely adverse incident report to the FDA related to a May 2014 infection linked to a Fujifilm ED 530 XT duodenoscope, when asked by the FDA in the spring of 2014 to provide the data that validated that Fujifilm's duodenoscopes could be cleaned of bacteria within acceptable safety margins using recommended procedures, Fujifilm (as well as Olympus and Pentax Medical) was apparently unable to do so through two rounds of submissions. It appears that no updated cleaning guidance has been issued by Pentax for these scopes. Fujifilm, in addition to Olympus and Pentax Medical, also declined to participate in the May 14-15, 2015 FDA Advisory Committee Meeting on "Effective Reprocessing of Endoscopes used in Endoscopic Retrograde Cholangiopancreatography (ERCP) Procedures" despite manufacturing the scopes used in these procedures.⁷

Even with enhanced cleaning procedures and more rigorous validation, it is clear that these necessary and important devices must be handled with extreme care to help prevent infections. At the FDA panel meeting, two-thirds of hospitals reported that scope cultures were positive for organisms after reprocessing.⁸ Representatives of Virginia Mason explained that the hospital has established a protocol requiring that, after a duodenoscope has been thoroughly cleaned and reprocessed, it is cultured for bacteria. This process requires a 48-hour waiting period between uses of a scope, and has required the hospital to purchase additional scopes. Yet the hospital believes it has little alternative to purchasing additional scopes given that they continue to experience a 3 percent contamination rate.⁹

I am committed to ensuring that the families impacted by these tragic outbreaks in Washington state and across the country get answers and accountability. In order to better

⁵ Response from Thomas A. Kraus, Associate Commissioner for Legislation, Food and Drug Administration to Senator Murray, May 15, 2015.

⁶ See Kristen A. Wendorf, Megan Kay, et al. "Endoscopic Retrograde Cholangiopancreatography-Associated AmpC *Escherichia coli* Outbreak" Infection Control & Hospital Epidemiology, May 2015 p. 8.

 ⁷ Fujifilm was apparently able to have representatives present at two large professional conferences in Washington, D.C. despite not attending the FDA Adivsory Panel meeting. *See* "Scope maker defends device design" Los Angeles Times, May 19, 2015.
 ⁸ FDA Executive Summary, Meeting of the <u>Gastroenterology-Urology Devices Panel of the Medical Devices Advisory</u> Committee, p. 15.

⁹ Kristen A. Wendorf, Megan Kay, et al. "Endoscopic Retrograde Cholangiopancreatography-Associated AmpC *Escherichia coli* Outbreak" Infection Control & Hospital Epidemiology, May 2015 p. 8.

understand the timeline of events Fujifilm's response to reports of infections related to duodenoscopes manufactured by Fujifilm, including the ED 530 XT, please provide the following information by June 19, 2015.

- Copies of all alerts, cleaning guidance, safety advice or warnings provided to any hospital or regulatory agency, foreign or domestic, mentioning any scope manufactured by Fujifilm used in Endoscopic Retrograde Cholangiopancreatography Procedures from 2005-2015.
- 2. Unredacted copies of all medical device reports or adverse event reports sent by Fujifilm to FDA regarding the ED 530 XT or any other scope used in Endoscopic Retrograde Cholangiopancreatography Procedures between 2005 and present.
- 3. Copies of all documents between 2010 and present that reference or refer to CRE or other infections and any endoscope, including any duodenoscope, manufactured by Fujifilm Medical Systems.

Sincerely,

Fatty Muna Senator Patty Murray

Senator Patty Murray Ranking Member, HELP Committee

cc: Senator Lamar Alexander, Chairman of the HELP Committee

LAMAR ALEXANDER, TENNESSEE, CHAIRMAN

MICHAEL B. ENZI, WYOMING RICHARD BURR, NORTH CAROLINA JOHNNY ISAKSON, GEORGIA RAND PAUL, KENTUCKY SUSAN M. COLLINS, MAINE LISA MURKOWSKI, ALASKA MARK KIRK, ILLINOIS TIM SCOTT, SOUTH CAROLINA ORRIN HATCH, UTAH PAT ROBERTS, KANSAS BILL CASSIDY, M.D., LOUISIANA PATTY MURRAY, WASHINGTON BARBARA A. MIKULSKI, MARYLAND BERNARD SANDERS (I), VERMONT ROBERT P. CASEY, JR., PENNSYLVANIA AL FRANKEN, MINNESOTA MICHAEL F. BENNET, COLORADO SHELDON WHITEHOUSE, RHODE ISLAND TAMMY BALDWIN, WISCONSIN CHRISTOPHER S. MURPHY, CONNECTICUT ELIZABETH WARREN, MASSACHUSETTS

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United States Senate

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS WASHINGTON, DC 20510–6300

June 8, 2015

Christopher Burton President of the Americas Region Pentax Medical 3 Paragon Drive Montvale, New Jersey 07645

Dear Mr. Burton:

As questions continue to arise regarding Pentax Medical's actions to adequately protect patients treated with duodenoscopes, I write to seek more information and express my serious and growing concern. As you are likely aware, between late 2012 and January 2014 Virginia Mason hospital in Seattle, Washington experienced an outbreak of deadly carbapenem-resistant Enterobacteriaceae (CRE) infections which were subsequently traced to duodenoscopes manufactured by Olympus Corporation. In all, 32 individuals were infected with CRE, an additional 7 people developed a separate *E. coli* infection, and 18 of those who developed infections later died.¹

Multiple cases of CRE infections traced back to duodenoscopes have now been confirmed at two other hospitals in 2014. In fact, the Food and Drug Administration (FDA) stated at the recently convened Advisory Committee Meeting of the <u>Gastroenterology-Urology Devices Panel</u> that there have been at least nine hospital outbreaks of multi-drug resistant infections traced to duodenoscopes in the United States, two of which are traceable to scopes manufactured by Pentax Medical.²

Overall, FDA has informed me that 139 separate reports of contamination or infectionrelated medical device reports, or adverse event reports involving duodenoscopes were received between 2011 and 2014, including 69 reports affecting 135 patients in 2014 alone.³ Ninety-four percent of these reports were received directly from the manufacturers, which include Olympus, Fujifilm and your company.⁴

⁴ Id.

¹ Many of the individuals who died suffered from serious illnesses and thus, those deaths may not be the direct result of the CRE infections.

 ² FDA Executive Summary, Meeting of the <u>Gastroenterology-Urology Devices Panel of the Medical Devices Advisory</u> <u>Committee</u>, pp.14-15.
 ³ Response from Thomas A. Kraus, Associate Commissioner for Legislation, Food and Drug Administration to Senator Murray,

³ Response from Thomas A. Kraus, Associate Commissioner for Legislation, Food and Drug Administration to Senator Murray, May 15, 2015.

I have become increasingly concerned by the failure of the three manufacturers to proactively warn patients and providers of the potential for infections. As early as January 2013, more than 38 patients were infected with CRE at a hospital near Chicago, Illinois that was linked to duodenoscopes manufactured by Pentax Medical.⁵ By September 2013 the Center for Disease Control and Prevention (CDC) had notified the FDA of the possible connection between multi-resistant bacteria hospital infections and duodenoscopes even when reprocessed according to the manufacturer's instructions.⁶ At approximately the same time, in November of 2013, an Olympus endoscopy support specialist found that Virginia Mason, which was attempting to contain a CRE outbreak, was properly reprocessing duodenoscopes stating "endoscope reprocessing procedures at [the hospital] were above the industry standard, and all technicians performed manual endoscope manufacturers should have been aware by at least late 2013 of the very real risk of multi-drug resistant infection from procedures using duodenoscopes even when cleaned according to instructions provided by the manufacturers.

I am not aware of that any additional steps were taken by Pentax Medical that may have alerted health professionals to the risk of infection even when properly cleaned. Moreover, when asked by the FDA in the spring of 2014 to provide the data that validated that Pentax Medical's duodenoscopes could be cleaned of bacteria within acceptable safety margins using recommended procedures, Pentax (as well as Olympus and Fujifilm) was apparently unable to do so through two rounds of submissions. It appears that no updated cleaning guidance has been issued by Pentax for these scopes. Pentax Medical, in addition to Olympus and Fujifilm, also declined to participate in the May 14-15, 2015 FDA Advisory Committee Meeting on "Effective Reprocessing of Endoscopes used in Endoscopic Retrograde Cholangiopancreatography (ERCP) Procedures" despite manufacturing the scopes used in these procedures.⁸

Even with enhanced cleaning procedures and more rigorous validation, it is clear that these necessary and important devices must be handled with extreme care to help prevent infections. At the FDA panel meeting, two-thirds of hospitals reported that scope cultures were positive for organisms after reprocessing.⁹ Representatives of Virginia Mason explained that the hospital has established a protocol requiring that, after a duodenoscope has been thoroughly cleaned and reprocessed, it is cultured for bacteria. This process requires a 48-hour waiting period between uses of a scope, and has required the hospital to purchase additional scopes. Yet the hospital believes it has little alternative to purchasing additional scopes given that they continue to experience a 3 percent contamination rate.¹⁰

⁵ "Pentax scope data are sought," Los Angeles Times, March 31, 2015.

⁶ Response from Thomas A. Kraus, Associate Commissioner for Legislation, Food and Drug Administration to Senator Murray, May 15, 2015.

⁷ See Kristen A. Wendorf, Megan Kay, et al. "Endoscopic Retrograde Cholangiopancreatography-Associated AmpC *Escherichia coli* Outbreak" Infection Control & Hospital Epidemiology, May 2015 p. 8.

⁸ Pentax Medical was apparently able to have representatives present at two large professional conferences in Washington, D.C. despite not attending the FDA Adivsory Panel meeting. *See* "Scope maker defends device design" Los Angeles Times, May 19, 2015.

⁹ FDA Executive Summary, Meeting of the <u>Gastroenterology-Urology Devices Panel of the Medical Devices Advisory</u> Committee, p. 15.

¹⁰ Kristen A. Wendorf, Megan Kay, et al. "Endoscopic Retrograde Cholangiopancreatography-Associated AmpC *Escherichia coli* Outbreak" Infection Control & Hospital Epidemiology, May 2015 p. 8.

I am committed to ensuring that the families impacted by these tragic outbreaks in Washington state and across the country get answers and accountability. In order to better understand the timeline of events and Pentax's response to reports of infections related to duodenoscopes manufactured by Pentax Medical, including the ED-3490 TK, please provide the following information by June 19, 2015.

- 1. Copies of all alerts, cleaning guidance, safety advice or warnings provided to any hospital or regulatory agency, foreign or domestic, mentioning any scope manufactured by Pentax Medical used in Endoscopic Retrograde Cholangiopancreatography Procedures from 2005-2015.
- 2. Unredacted copies of all medical device reports or adverse event reports sent by Pentax Medical to FDA regarding the ED-3490 TK or any other scope used in Endoscopic Retrograde Cholangiopancreatography Procedures between 2005 and present.
- 3. Copies of all documents between 2010 and present that reference or refer to CRE or other infections and any endoscope, including any duodenoscope, manufactured by Pentax Medical.

Sincerely,

Senator Patty Murray Ranking Member, HELP Committee

cc: Senator Lamar Alexander, Chairman of the HELP Committee

United States Senate

WASHINGTON, DC 20510-4704

COMMITTEES: APPROPRIATIONS BUDGET HEALTH, EDUCATION, LABOR, AND PENSIONS RULES AND ADMINISTRATION VETERANS' AFFAIRS

February 3, 2014

The Honorable Margaret Hamburg Commissioner Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Dear Commissioner Hamburg,

Last week, news reports highlighted a recent cluster of infections caused by carbapenemresistant *Escherichia coli* (CRE), which were linked to the use of contaminated medical devices, known as duodenoscopes, at a well-known Seattle medical center, Virginia Mason. While outbreaks of CRE have occurred across the country, world class surveillance and timely engagement by the hospital and the Washington State and Seattle & King County Departments of Health identified the cause of this unusual outbreak and worked quickly to minimize its spread.

CRE infections are serious, with fatality rates as high as 40-50%. In Seattle, at least 32 patients were infected with CRE via duodenoscope contamination, and though 11 of these patients died, it remains unclear whether CRE was the cause. Without the rapid and conscientious responses of Virginia Mason and the state and local health departments, the public health impact could have been much worse. Other recent outbreaks associated with the use of duodenoscopes occurred in Pittsburgh and Chicago, with dire consequences.

Due to their complicated and intricate design, duodenoscopes are harder to clean and disinfect than many reusable medical devices. Yet in Seattle, parallel assessments of duodenoscope reprocessing procedures by both the Washington State Department of Health and the Centers for Disease Control (CDC) found that duodenoscopes used by Virginia Mason routinely failed to pass testing for pathogenic bacteria, despite strict adherence by the hospital staff to the manufacturer's labeling. In some cases, cleaning measures recommended by the manufacturer were insufficient to remove debris and soil, forcing medical staff to adopt more aggressive cleaning techniques. These findings indicate that – even when providers carefully follow manufacturers' labeling regarding cleaning and disinfection of duodenoscopes – contamination still poses grave risks to patients.

The Food and Drug Administration (FDA) issued a draft guidance in 2011 entitled "Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," which updated prior guidance on the reprocessing of reusable medical devices. This

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COMMITTEES: APPROPRIATIONS BUDGET HEALTH, EDUCATION, LABOR, AND PENSIONS RULES AND ADMINISTRATION VETERANS' AFFAIRS

update is an important step forward in addressing antibiotic resistant infections caused by reprocessed duodenoscopes, bolstering criteria used to evaluate product labeling and reprocessing procedure validation measures. I appreciate these efforts to improve the safety of reusable medical devices.

In light of the infections in Seattle and other communities across the country, I am writing to urge the FDA to finalize this guidance and provide health care professionals with updated best practices for reusable medical devices as soon as possible. In doing so, FDA should focus on the unique issues surrounding the reprocessing of complex devices, such as duodenoscopes. The FDA should also consider whether more robust post-market surveillance, beyond that discussed in the draft guidance, is appropriate given the nature of these devices and recent outbreaks.

FDA also should work closely with manufacturers of duodenoscopes and other complex reusable devices to ensure that product labeling reflects the most recent available knowledge regarding effective reprocessing techniques. Because that process will take some time, FDA also should consider whether additional safety information should be communicated to providers, patients and other stakeholders in the meantime.

Your ongoing collaboration with FDA's sister agency, the CDC, is also critical to ensure a comprehensive approach to preventing and detecting future outbreaks.

While recognizing that many stakeholders have a part to play in combatting device-borne infection, the FDA plays a critical role. I urge you to take the steps identified above as soon as possible.

Sincerely,

Patty Murray United States Senator

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United States Senate

COMMITTEE ON HEALTH, EDUCATION,

March 20, 2015

The Honorable Margaret Hamburg Commissioner Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Dear Commissioner Hamburg,

Thank you for your actions in response to my February 3, 2015, letter regarding "superbug" infections at Virginia Mason Hospital in Seattle, Washington, and in other facilities around the country. In that letter, I urged the Food and Drug Administration (FDA) to take several steps in the wake of these serious outbreaks. The agency's actions last week represented important progress. However, in light of the tragic impact these outbreaks have had on patients and families in my state and nationwide, I write today to seek additional information from the agency. We must do everything we can to understand how these outbreaks occurred and find out what more can be done to protect patients.

As you know, it appears that these infections were potentially caused by duodenoscopes cleaned according to current protocols, but nonetheless harboring carbapenem-resistant Enterobacteriaceae (CRE) bacteria. In Washington State, at least 32 patients were infected and, although the cause is not clear, 11 died.

I appreciate that, as requested in my earlier letter, the FDA has issued new guidance to better ensure the safety of all "reprocessed" medical devices. Specifically, the guidance outlined that manufacturers of certain types of scopes, including duodenoscopes, are expected to demonstrate that testing of cleaning protocols and procedures is sufficiently rigorous and then provide complete testing reports to FDA for review.

In my earlier letter, I also discussed the importance of FDA providing updated safety information to health care providers and stressed the need to work closely with manufacturers on product labeling. I appreciate that last Thursday's guidance also provided updated information for reprocessing of devices in health care settings. This information will help to ensure that health care professionals are informed about current best practices.

In addition, I appreciate your collaboration with the Centers for Disease Control and Prevention (CDC) on a protocol, released last week, that hospitals can use to culture these devices to detect bacterial contamination – a protocol modeled on the best practices used at Virginia Mason Hospital in Seattle.

All of these actions are productive steps. However, since I sent my previous letter, new information has surfaced that heightens my concern about this tragic situation. For example, I understand that the reprocessing procedures recommended by manufacturers of currently-marketed duodenoscopes may not have been undertaken and validated in a sufficiently rigorous manner. There are also reports that one manufacturer failed to seek FDA clearance before marketing a specific duodenoscope model, although I understand from FDA that there is no evidence at this time that the lack of clearance is associated with infections. Finally, some public sources have indicated that FDA received numerous adverse event reports dating back to 2013 related to microbial transmission via reprocessed duodenoscopes. At least 15 of the patients noted in these adverse event reports may have died from CRE infections.

This additional information raises questions about why updated guidance, including enhanced cleaning protocols, was not released sooner and the rigor of FDA's examination of post-market data to assess the risks of these devices for patients if not adequately cleaned during reprocessing.

I am glad that you committed to me at the March 10, 2015, Health, Education, Labor and Pensions (HELP) Committee hearing to undertake a full review of this situation. We must determine the facts, and only then can we formulate additional steps to minimize the risk to patients in the future. As part of FDA's efforts, I request that you provide the following information to the HELP Committee:

- 1. FDA's internal review of the adequacy of reprocessing procedures, including review of the validation procedures undertaken by manufacturers of all currently-marketed duodenoscopes, bronchoscopes, endoscopes, and other devices in Appendix E of the new final guidance entitled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."
- 2. Updates regarding FDA's work with manufacturers of all marketed duodenoscopes on any necessary revisions to product design and labeling, particularly with regard to reprocessing procedures.
- 3. A summary of all adverse event reports from 2011 forward for duodenoscopes, bronchoscopes, endoscopes, and other devices in Appendix E of the guidance, including when and how FDA responded to these reports.
- 4. An assessment of the adequacy of the 510(k) process regarding revisions to product design and labeling, particularly with regard to reprocessing procedures for duodenoscopes, bronchoscopes, endoscopes, and other devices in Appendix E.

I understand, as you noted at the hearing, that duodenoscopes are important devices that serve a critical role in medical care. But as we have seen, insufficient cleaning procedures can create huge risks and cost lives. We cannot afford to be complacent regarding the danger that CRE infections, or other "superbugs," pose. I look forward to continuing to work together to improve reusable device cleaning and monitoring recommendations, and I request that you continue briefing my staff regularly. I appreciate your prompt response to my questions above and all of the steps being taken to protect the public from further infections.

Sincerely,

Party Mun

Patty Murray Ranking Member

Cc: Lamar Alexander, Chairman

Appendix II: Reports

This appendix includes a report of the results of Dr. Arjo Loeve's investigation of the TJF-Q180V closed-channel duodenoscope involved in the outbreak of antibiotic-resistant infections at Erasmus Medical Center in the Netherlands. It also includes the report of the Dutch National Institute for Public Health and the Environment (RIVM) investigation into the design and safety of the TJF-Q180V duodenoscope and the response of Erasmus Medical Center. The translation of this report from the original Dutch to English is not endorsed or verified by RIVM.

Investigation Olympus TJF-Q180V Scope

following detected contamination after cleaning and disinfection

(Internal title: Report Investigation Scope G-206)

Reporting, Conclusions and Recommendation

May 15, 2012

Final Version - Revision June 27, 2012 – Adding external title August 29, 2014

Dr. Ir. Arjo Loeve

Delft University of Technology

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1 Background - Contamination 'Scope G-206'

Recently the bacterium Pseudomonas Aeruginosa was found at the Erasmus Medical Center ('Erasmus MC') in the cavity of the tip of an Olympus video duodenoscope TJF-Q180V (hereinafter referred to as 'Scope G-206', where the number 206 refers to the internal registration number of the related scope within the Erasmus MC). This bacterium persisted after manual cleansing and mechanical cleaning and disinfection in the Olympus ETD3 scope disinfector.

In order to locate the cause of the persistence of the detected bacteria, it was decided to extensively inspect Scope G-206, to take samples at places that are normally within reach. It will then step by step disassembled and inspected. Sampling will be taken in areas that have become accessible through the disassembly. Also due to these sampling-and disassembling steps and the subsequent microbiological and viral investigations (hereinafter referred to as *'the investigation)*, it is attempted to discover if the persistence of the bacteria is caused by:

- Incorrect or insufficient following of the cleaning instructions
- Incorrect or insufficient formulated cleaning instructions
- Insufficient functioning of sealing in Scope G-206
- Other cause(s)

Olympus Nederland and the Erasmus MC have decided together to take care of and to carry out a further investigation of the contamination of Scope G-206. On April 23, 2012 an investigation team (hereinafter referred to as *'the investigation team'),* consisting of representatives of the Erasmus MC and Olympus, as well as an independent expert of the Delft University of Technology ('TU Delft'), has conducted the investigation at Olympus Nederland B.V., Industrieweg 44, Zoeterwoude, Netherlands.

2 Purpose and layout of this report

Purpose of this report is to come to an objective determination of the cause / causes of the persistence of the Pseudomonas Aeruginosa bacterium in Scope G-206.

For this purpose, first a factual record (supported by photos as well as registration and result lists) of the briefing and execution of *the investigation* is provided.

Following the findings during *the Investigation*, the independent expert of the TU Delft has formulated an opinion concerning the most likely cause / causes of the persistence of the Pseudomonas Aeruginosa bacterium in Scope G-206.

In this report, the sample reference numbers are given as {0000}

3 Disclaimer

Photo used in this report were taken by a professional photographer. The photos were corrected visually regarding color to compensate for deviations by changing light sources and using different cameras. (Overview and macro photos were made with a Nikon D300s and microscope photos with the connected camera). Colors may therefore still differ slightly from the actual colors as they would have been observed under daylight or under daylight lamps. Due to differences in color rendering by different monitors, printers or kinds of paper, possible deviations could be stronger.

Conclusions regarding observations should in no way be based on shades of color or specific characteristic, absolute color values based on the utilized photos.

The conclusions, estimations and recommendations as shown in Chapter 6 "Opinion of the independent expert" are conclusions, estimations en recommendations based on the observed facts during the investigation, the know-how and experience of the independent expert (Arjo Loeve, see Chapter 4) and confidential discussions between the independent expert, experienced fellow scientists and Head of the Department Prof. Dr. Jenny Dankelman in the Biomechanical Engineering Department of the Delft University of Technology, Faculty 3ME.

Therefore conclusions, estimations en recommendations in Chapter 6 can be seen as an informed expert opinion, but in no way a formal position of the Delft University of Technology.

The names used to refer to parts of the scope in this report are not necessarily the same as names commonly used or names used within Olympus. For example: A 'sealing' can also be known as 'bonding' or a 'cap' can be referred to as 'cover'/'sleeve'/'housing'. In this report, consistent and unambiguous use of names was taken care of as much as possible.

In case of uncertainty or doubt about which part is identified by a particular name, you will need to contact the author before drawing conclusions and / or take consequences regarding this report.

4 Briefing Report

The investigation was conducted on April 23, 2012 at Olympus Nederland B.V., Industrieweg 44, Zoeterwoude.

At around 10:15 hrs., the *investigation team* gathered there consisting of:

Name	Job Function	Organization
Henk Braat Knut Burmester Viktor Tran Kees Verdouw Marcel Vonk Leo Abel Jolanda Buijs-Hegeman Leo Groenendaal Johan de Kat Annelies Poth	Managing Director Section Manager Service Engineering Production Support Specialist MSD Service Engineer Flexible Instruments Sales Support Manager CDS Unit Head Gastroenterology & Liver Diseases Dept. Staff Advisor Medical Devices Unit head of Medical Technology Hospital Hygienist Expert Medical Devices Hospital	Olympus Nederland B.V. Olympus Europa Holding GMBH Olympus Europa Holding GMBH Olympus Nederland B.V. Olympus Nederland B.V.
Annette Sandijck Arjo Loeve	Hygienist Researcher Biomechanical Engineering	Erasmus Medical Center Delft University of Technology

A number of issues relating to the people present are specifically addressed:

- Henk Braat leading the meeting indicates that he will not be present during *the investigation*.
- Arjo Loeve as an independent expert from the TU Delft will take care of reporting, photo / video shooting for recording, and will observe the process objectively and critically and will manage when necessary.
- Leo Abel will take care of the sampling and will wear latex gloves.
- Viktor Tran takes care of the scope disassembly and will wear latex gloves.
- Annette Sandijk takes care of the storage of the sample materials.
- Johan de Kat will take care of the labeling and packaging of the samples.
- Kees Verdouw will provide and operate any auxiliary equipment such as microscopes.

It is discussed what the approach during *the investigation* will be:

- 1 Sampling working channels and tip of Scope G-206 with a 3mm diameter cytology brush in order to determine possible presence of residual patient material. Only those samples will be taken in the clean room and attendees present will be wearing gloves and masks.
- 2 Step-by-step disassembling of Scope G-206. For each disassembly step, the relevant part of the scope will be visually inspected, photographed and sampled with cytology brushes and / or swabs. Components of Scope G-206 would also partially or completely be packed for further investigation (cultures, NACT PCR and viral).
- 3 At a later stage components of Scope G-206 will be examined with an electron microscope in order to determine the presence of possible biofilms.

- 11:23 hrs. Preparing the work tables (disinfecting and covering them with a sterile cloth). Those present in the clean room are wearing protective coats and surgical masks. Leo Abel samples the scope and wears in addition to the protective coat and the surgical mask, also sterile gloves and a surgical cap.
- 11:31 hrs. Sampling for PCR in a clean room. Present in the clean room are: Leo Abel, Arjo Loeve, Annelies Poth, Annette Sandijck, Marcel Vonk. The rest of *the investigation team* observes from a technical location.
 - Sampling the parts below with sterile 3 mm diameter cytology brushes (after sampling by brushing and/or pigging, each brush is collected in a new and sterile laboratory jar):
 - Air/water channel and instrument channel tip {5379} (Figure 1).



Figure 1: Tip of Scope G-206 and the cytology brush used.

• The cavity under the forceps elevator ("behind the forceps elevator" according to the sample list) {5388} (Figure 2). It should be noted that it was impossible to reach behind/below the forceps elevator cytology brushes since these have a hard tip. Grooves, holes and cracks in that part of the tip could not be reached



Figure 2: Sampling of the cavity under the forceps elevator.



Biopsy / instrumentation channel {5396} and biopsy port {5401} (Figure 3).

Figure 3: Sampling biopsy channel (above and left middle) and biopsy port (right middle and below).

- 11:40 hrs. *The investigation team* is located in the technical area. The rest of the investigation will take place there. It was decided that the Scope G-206 or parts exposed between the disassembly steps do not need to be cleaned due to the low probability of relevant cross-contamination (since the search is focused on a very specific bacterium).
- 11:43 hrs. Viktor makes the first cut in the sealant of cardan rubber, directly behind the steerable tip of the scope and observes air bubbles in the sealing. He suspects that the sealant was applied by a third party. Further investigation shows that Erasmus MC does not use a third party for repairs; this sealant was applied by Olympus Nederland B.V.. Arjo requests to pause in order to first take photos of the coating, Figure 4. The scope is moved to the microscope in order to take photos of the tip.

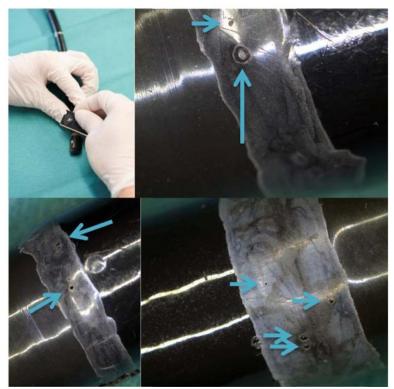


Figure 4: Cutting the sealant of cardan rubber open and microscope photos of the air bubbles (some of them are open) in the still untouched parts of the sealing. The air bubbles are indicated with arrows.

Photos of the camera and light source in the tip show:

- brownish scale **behind** the cover glass of the camera (Figure 5)
- cracks in the sealing of the housing of the tip around the camera (Figure 5)

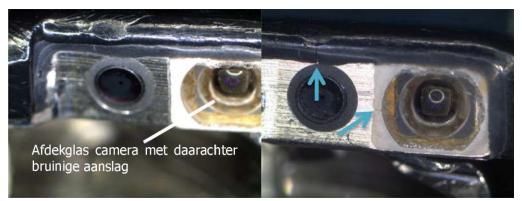


Figure 5: Visual inspection camera housing. On the left and right, it is clearly visible that the scale is located behind the glass covering of the camera. On the right, a vertical arrow points to the tear in de sealing of the housing. Furthermore, on the right another tear can be seen in de sealing of the camera which is indicated with the diagonal arrow.

Photos of the cavity in which the forceps elevator moves, made with the microscope and a small diameter fiberscope, show (Figure 6 en 7):

- scratches and grooves reaching under the forceps elevator,
- whitish scale in the tip housing and also brownish scale on the metal part where the forceps elevator runs {5412, 5423, 5434}.

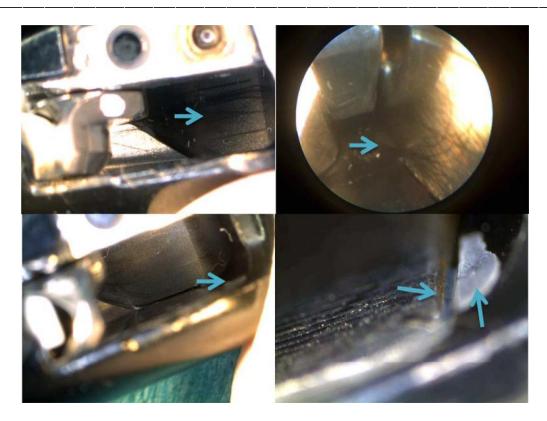


Figure 6: Visual inspection of the tip around the forceps elevator. Above: scratches and grooves well below the forceps elevator; the arrows point to the scratches. Below: whitish and brownish scale (arrow) on the surface where along the forceps elevator moves.



Figure 7: From left to right: sampling of the space around the forceps elevator with swab; scraping sample of white and brown scale; overview of work setting, cutting of scalpel point for packaging.

12:22 hrs. Viktor Viktor removes the sealing with which the hard plastic cap of the cardan part of the scope is connected. This sealing is packaged as sample {5445}. Then under the adhesion on the flexible sleeve which covers the steerable part will take place using a swab {5456, 5467} (Figure 8).



Figure 8: Removing and packaging of the sealant between the hard plastic cap of the tip and the cardan rubber of the scope and (far right) sampling under the cardan rubber.

Viktor removes the hard plastic cap from the tip by cutting it open and prying it loose from the adhesive layer that glues it to the metal interior of the tip. Waste from cutting the cap is packaged for further testing {5478} (Figure 9). Then sampling with swabs took place inside the housing on which the hard plastic cover was glued {5489, 5490} (Figure 9).



Figure 9: (First two photos on the left) Cutting open and prying loose of the hard plastic cap on the tip. (Two photos on the right) Sampling interior under the removed hard plastic cap.

It was attempted twice to reach behind the forceps elevator with a swab for sampling. However, the limited space does not lend itself for a deep sampling. Therefore superficial sampling at the rear end of the forceps elevator took place as well as in the forceps elevator channel {5507, 5516} (Figure 10). Another attempt was made to sample deep behind the forceps elevator using a cytology brush. This was a bit more successful, but the space was still too limited for the brush to reach behind the forceps elevator {5521} (Figure 10).



Figure 10: Sampling behind the forceps elevator with swabs and cytology brush.

Inspection of the forceps elevator hinge under the microscope (Figure 11) showed that the hinge has relatively speaking a lot of room to maneuver. When the forceps elevator was moved, a fiber catapulted from this hinge. This fiber was picked up with the point of a scalpel and packaged for further investigation {5535}.

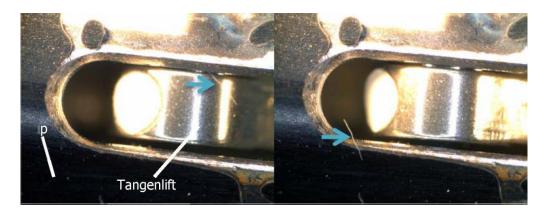


Figure 11: Microscope images of the forceps elevator hinge and the fiber that emerged from it. The axial shifting of the forceps elevator due to room for maneuvering is clearly visible in the two photos. Arrows point to the location of the fiber

12:56 hrs. **LUNCH BREAK**. All participants leave the technical area and continue with *the investigation* only after Arjo was present again.

13:27 hrs. **CONTINUATION.** *Het investigation team* is present again in the technical area. Viktor removes the cover plate that covers de actuator area of the forceps elevator (Figure 12, left). The cover plate is packaged for further testing {5609}. Then the propulsion cable of the forceps elevator is sampled twice with swabs {5542, 5558} (Figure 12, right). What is immediately noticeable is the fact that all metal surfaces inside the opened actuator area are covered in brown scale. Further testing is needed to determine if this is the result of oxidation or something else.

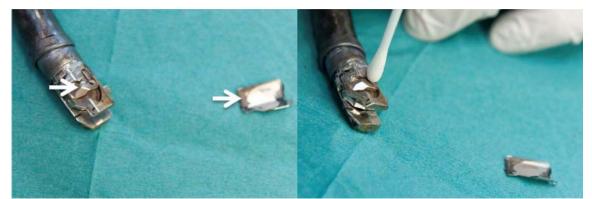


Figure 12: (Left) Verwijdering afdekplaat (rechter piji) van actuator area forceps elevator (linker piji). (Right) Sampling propulsion cable forceps elevator.

Two swab samples were taken from the deep area in which the lever of the forceps elevator moves back and forth {5560, 5573} (Figure 13, first three on the left). After disconnecting and pushing aside the propulsion cable of the forceps elevator (using a precision screwdriver), the area where the propulsion cable was originally running on was sampled twice with swabs {5584, 5599} (Figure 13, far right).

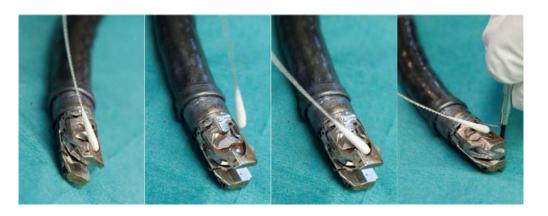


Figure 13: (First three photos on the left) Sampling of the deep area in which the lever of the forceps elevator moves back and forth. (Far right) Sampling under the propulsion cable of the forceps elevator.

13:54 hrs. Viktor removes the glue from the screw which mounts the forceps elevator on the axis of the lever, lifting axle. The screw is removed and packaged for further testing {5677}. The lever with lifting axle forms one single part which is lifted from the actuator area and put under the microscope (Figure 14). There is an O-ring around the lifting axle that should create a watertight separation between the actuator area and the patient.



Figure 14: From left to right: lifting away of the lever with lifting axle; actuator area from where the lever was removed; lever with lifting axle and O-ring photographed from the side that was in the actuator area; lever with lifting axle and O-ring photographed from the side of the lifting axle. The O-ring was mounted on the forceps elevator.

In the far right photo in Figure 14, it can be clearly seen that all surfaces of the lever and lifting axle that were located in the actuator area, the actuator area-side, was covered with brown scale. The lifting axle looks clean at the side where the forceps elevator (and therefore also the patient) was located, the patient-side.

Under the microscope, the lever is sampled twice with swabs at the actuator area-side $\{5613, 5620\}$ and twice on the lifting axle that was located in the forceps elevator $\{5636, 5648\}$ (Figure 15).

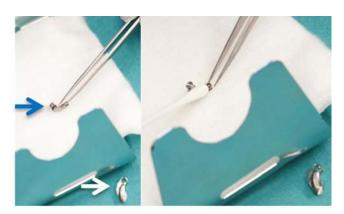


Figure 15: Lever with lifting axle and O-ring (dark blue arrow) and the forceps elevator (white arrow).

Under the microscope the difference between the brown-scaled actuator-side area and the cleanlooking patient-side of the lever with lifting axle is clearly visible again (Figure 16). The O-ring shows signs of wear and is on the actuator-side area heavily covered with brown scale. On the surface of the O-ring (where it is wedged in the housing) the brown scale is also prominently present. On the patient-side of the O-ring is the brown scale still present, but to a lesser extent.

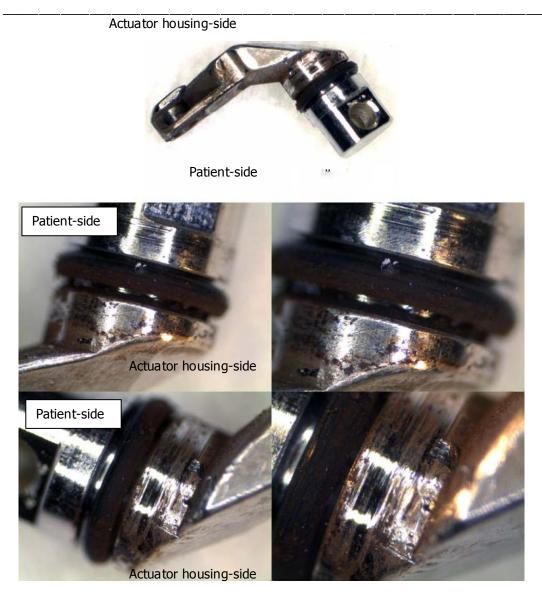


Figure 16: Microscope images of the lever with lifting axle and O-ring. In each of the bottom four photos, there is an enlargement of the central part of the photo on the left.

Viktor removes de O-ring from the lifting axle. The O-ring is cut into two halves, both of them are packaged for further testing $\{5651, 5664\}$ (Figure 17). The forceps elevator and the lever with lifting axle are also packaged for further testing $\{5682, 5695\}$. Finally, a virological sample is taken from the water suction channel $\{5706\}$ before the tip of Scope G-206 is packaged with a sterile bag and the scope in is stored in its case (Figure 17).

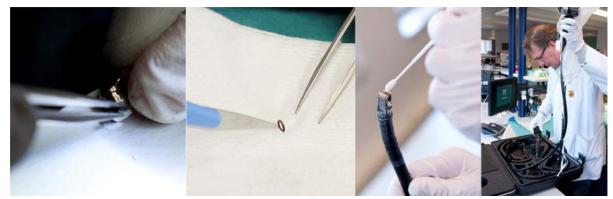


Figure 17: From left to right: removing the O-ring; cutting the O-ring in half; virological sample from water suction channel; packaging of Scope G-206.

14:23 Since Viktor and Knut must catch their plane back to Germany, *the investigation* is terminated. Therefore it is refrained from sampling of the inside of the scope shaft, the removal and cutting up of the working channel for further testing, and the sampling of the inside of the handle of Scope G-206.

6. Opinion independent expert

Accessibility for brushes

Observations: During the sampling it became repeatedly clear that the tip of Scope G-206 contains several cracks, corners and spaces that are hard to reach or cannot be reached at all with the 3 mm diameter cytology brush. In particular:

- the crack under the hinge point of the forceps elevator,
- the crack caused by the axial clearance of the forceps elevator,
- and the area under/behind the curve of the forceps elevator,

proved unreachable for this brush (Figures 2, 10 and 11).

Recommendation: Enlarge in the scope design the space around the mentioned points so that these can be reached by brushes and / or make sure that the cleaning instructions are such that those points are cleaned thoroughly in the current scope in one way or another. Validate that the customized designs and / or instructions actually result in sound cleaning.

Quality of sealing

Observations: The sealing in and around the tip were found to show abnormalities that could result in potential leakage. Specific observations:

- air bubbles, some of them open, in the adhesion between the hard plastic cap of the tip and the flexible sleeve over the steerable part of the scope (Figure 4),
- cracks in the sealing around the camera housing (Figure 5),
- Worn looking O-ring which should ensure the sealing around the lifting axle (Figure 12).

The air bubbles in the adhesion and the tear in the sealing can open the door for the appearance of moisture and micro-organisms. Visualization of the O-ring with a scanning electron microscope. Based on the images of the O-ring, in particular the rough / powdery texture of the surface and the crack that can be seen in the electron microscope photo (see Appendix B), it appears that reliable sealing by means of this O-ring cannot be not guaranteed. This is further supported by the findings as described below under 'Scale found on parts'.

Recommendation: Ensuring regular, strict control of sealing between moments of use. Take care of regular replacement of the O-ring (it might have performed well over time, but it remains a moving sealing which requires maintenance). Improve in future scope designs the sealing by creating multiple barriers or, and this would be preferred, avoid such sealing at all and design a forceps elevator with no moving parts that run from the patient into a "sterile" area of the instrument.

Scale on parts

Observations: At a number of locations in the tip of Scope G-206, scale was detected:

- brownish scale behind the glass covering of the camera (Figure 5),
- brownish and whitish scale on the edge of the space around the forceps elevator (Figure 6),
- brownish scale on the surfaces in de actuator area (Figure 12),
- brownish scale on the surfaces of the lever at the actuator area-side (Figure 16),
- brownish scale on the O-ring, mainly at the actuator area-side, but also at the patient-side (Figure 16).

Scale behind the covering glass of the camera implies that this area was not properly sealed, so that growth of micro-organisms, scale from residual liquids or deterioration of a possible coating occurred.

Scale on the edge of the area around the forceps elevator should be investigated further before arriving at any conclusions. This could be oxidation, but in case of a contamination it could also indicate insufficient / incorrect cleaning by the Erasmus MC, since this location is well and easily accessible.

The brownish scale on the surfaces in de actuator area, the actuator area-side of the lever and the O- ring is so consistent and evenly distributed that it is highly unlikely that this oxidation is caused by, for example, skin contact during assembling. It is more likely that somewhere from the shaft or the tip of the endoscope moisture and / or biological material has entered the actuator area and lingered and / or augmented.

The fact that the brownish scale of the O-ring can be seen on each side of the O-ring (area actuator-side and patient-side) suggests that this scale around and on the O-ring has migrated from one side to the other. It is therefore very likely that this O-ring has not done its job. Furthermore, it appears that also the the size of the cracks between the forceps elevator and the housing as well as between the lifting axle and the housing are too small to be able to be brushed (and perhaps also to be rinsed) and too large to be inaccessible for liquids and / or biological materials.

Experience with O-ring-sealing on this scale shows that less than 0.01mm deviation from the ideal clearance can already cause leakage. More scale could therefore increase the chance of leakage or scale can be caused by leakage. During the axial back and forth movement of the lifting axle, the O-ring could make axially rolling movements, which could cause moisture and / or organic material to enter between the O-ring and the lifting axle. With each further movement of the lifting axle, moisture and / or organic material could migrate further from the actuator housing- side to the patient-side or vice versa.

Recommendation: Find out what the scale behind the glass covering of the camera is, measure the quality of the sealing and correct when necessary. Review the cleaning process critically in order to trace how the scale in the forceps elevator channel on an easily accessible location could linger and stay unnoticed.

Improve the sealing of the actuator area or avoid in future designs the use of such sealing. Check the existing sealing in all existing scopes and ensure an objective, critical, quantitative measuring of the sealing quality.

Cultures

Observations: Culture results are shown in Appendix A, Table A.2. Only the cultures (specific as well as generic) of the hard plastic cap of the tip provided positive culture results. Since the exterior of the cap has been cleaned repeatedly, can be accessed easily, has been dry for a long time, (the detected bacterium normally does not thrive on dry surfaces), it is therefore highly likely that the bacterium was located on the inside of the cap. This finding also fits the observations made regarding the quality of the sealing.

The fact that there were no positive culture results at other points does not mean that none were there. The inaccessibility of many places on the tip, the limitations of the sampling with swabs and the fact that biofilms grow more easily on plastics and rubbers than on metals, result in the fact that little can be concluded based on the negative test results.

Recommendation: Also make a culture of the spare sample of the O-ring {5651}. If possible, conduct a detailed investigation to exclude the presence of unwanted biomaterials in the actuator area. Since apparently Pseudomonas Aeruginosa was found inside the tip, it seems prudent to investigate immediately all scopes worldwide of a similar type. See also recommendations in the 'Quality of Sealing' and in the 'Conclusion' sections.

Conclusion

Observations: All in all, it seems that this scope has suffered badly from usage, possible insufficient quality of sealing, inadequate maintenance and lack of critical mechanical control. The very small cracks and spaces in the forceps elevator channel form a number of locations where lingering and / or increasing moisture and / or biological materials are guite likely.

It goes without saying that the sealing, actuator area en O-ring require direct and serious attention in all existing and future scopes similar to Scope G-206.

Recommendation: Increase direct global control and maintenance of similar scopes, revise especially scopes with degraded sealing, and conduct extensive sampling. Update the cleaning instructions and conduct strict controls to ensure compliance and acceptable results. Improve the quality of the sealing in the scope design and minimize the amount of sealing points.

In case during further testing Pseudomonas Aeruginosa or other bacteria/viruses/substances are also found that should not be present in the actuator area, it is recommended to immediately recall all similar scopes and/or in parallel to investigate if there could (also) be a leakage trail that does not run via the O-ring or other sealing.

Appendix A – Registration numbers and descriptions of cultures Scope G-206

Material / Location	Reference number
Air/water channel tip	5379
Behind forceps elevator	5388
Biopsy channel	5396
Biopsy port	5401
Contamination tip, top	5412
Scalpel 1	5423
Scrapings after scalpel 1	5434
Adhesion cap	5445
Swab under adhesion 1	5456
Swab under adhesion 2	5467
Сар	5478
Culture without cap 1	5489
Culture without cap 2	5490
Under forceps elevator after removing cap 1	5507
Under forceps elevator after removing cap 2	5516
Brush under forceps elevator without cap	5521
Scalpel with fiber	5535
Cable forceps elevator tip 1	5542
Cable forceps elevator tip 2	5558
Housing forceps elevator channel for O-ring 1	5560
Housing forceps elevator channel for O-ring 2	5573
Sample under cable in tip 1	5584
Sample under cable in tip 2	5599
Cover plate forceps elevator operating housing	5609
Operating forceps elevator patient side 1	5613
Operating forceps elevator patient side 2	5620
Operating forceps elevator instrument side 1	5636
Operating forceps elevator instrument side 2	5648
Half of O-ring 1	5651
Half of O-ring 2	5664
Screw backside forceps elevator	5677
Forceps elevator	5682
Lever	5695
Water suction channel (virological sample)	5706

Table A.1: Sample material and locations and relating reference numbers.

Reference number	Lab Number	Туре	Date	Result	
5379	Handed to Annelies Poth for DNA Investigation				
5388	Handed to Annelies Poth for DNA Investigation				
5396	Handed to Annelies Poth for DNA Investigation				
5401	Handed to Annelies Poth for DNA Investigation				
5412	20120072678101	AERK	2012-04-	negative	
5423	20120072674701	AERK	2012-04-	negative	
5434	20120072680001	AERK	2012-04-	negative	
5445	20120072666701	VIM	2012-04-	negative	
5456	20120072681901	AERK	2012-04-	negative	
5467	20120072683501	VIM	2012-04-	negative	
5478	20120072675501	VIM	2012-04-	VIM pseu, B-DYK-9760	
5478	20120072677101	AERK	2012-04-	E. Faecium, B-DYK-9757	
5478	20120072677101	AERK	2012-04-	VIM pseu, B-DYK-9756	
5489	20120072686101	AERK	2012-04-	negative	
5490	20120072688601	VIM	2012-04-	negative	
5507	20120072689401	AERK	2012-04-	negative	
5516	20120072695801	VIM	2012-04-	negative	
5521	Handed to Annelies Poth for DNA Investigation				
5535	20120072673901	AERK	2012-04-	negative	
5542	20120072700201	AERK	2012-04-	negative	
5558	20120072705301	VIM	2012-04-	negative	
5560	20120072711701	AERK	2012-04-	negative	
5573	20120072717601	VIM	2012-04-	negative	
5584	20120072729901	AERK	2012-04-	negative	
5599	20120072734401	VIM	2012-04-	negative	
5609	Spare for possible future cultures and / or counter-expertise				
5613	20120072737901	AERK	2012-04-	negative	
5620	20120072740801	VIM	2012-04-	negative	
5636	20120072745901	AERK	2012-04-	negative	
5648	20120072750401	VIM	2012-04-	negative	
5651	Spare for possible future cultures and / or counter-expertise				
5664	Handed to Annelies Poth for DNA Investigation				
5677	Electron microscopy				
5682	Electron microscopy				
5695	Electron microscopy				
5706	6159-E	CELK	2012-04-	negative	

Appendix B - Electron microscope photos

The electron microscope photos in this appendix are made with a scanning electron microscope by the Vossius-institute in Leiden.

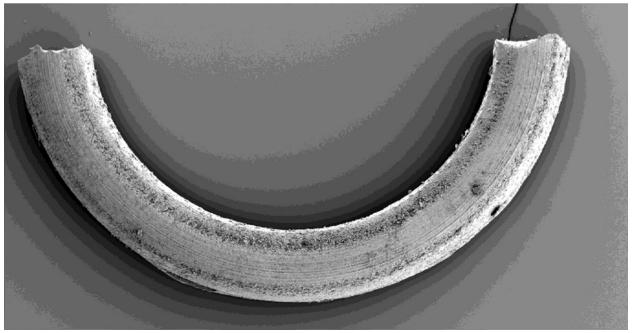


Figure B. 1: Photo of the O-ring which clearly shows that the surface of the O-ring is rough and fibrous, contains scale and was torn at the left bottom.

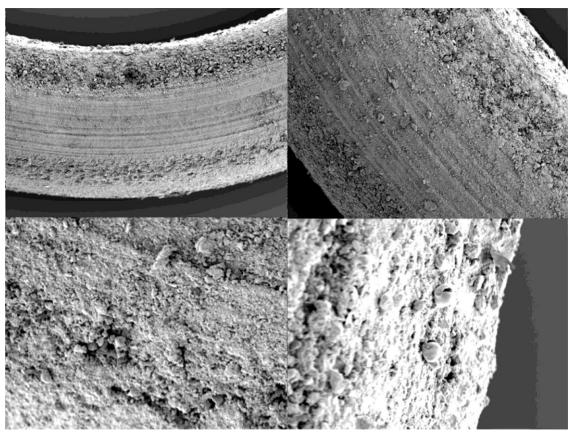


Figure B.2: a few more enlargements of the surface of the O-ring.

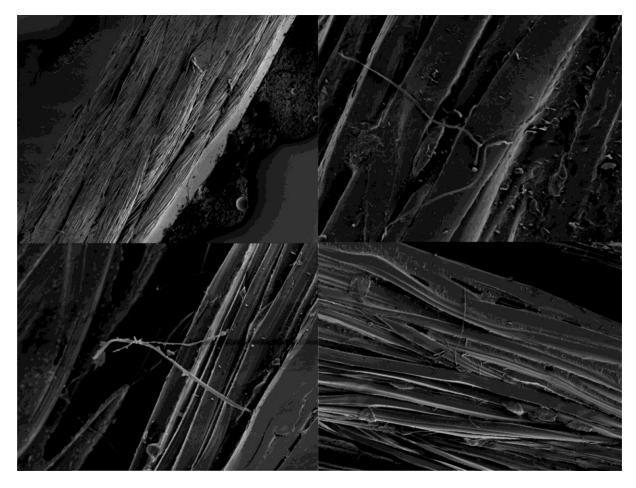
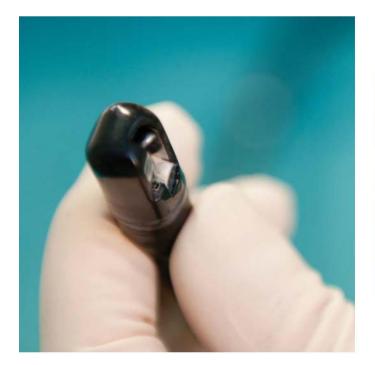


Figure B.3: Photos of the surface from the bottom of the sealing between the hard plastic cap of the tip and the cardan rubber of the scope.

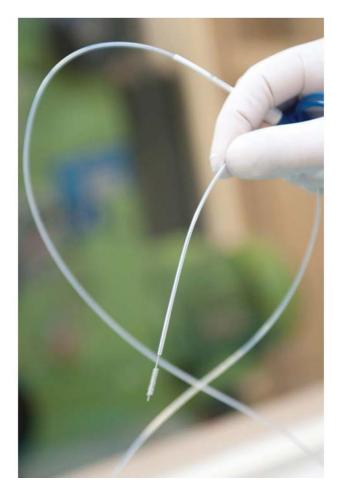
Appendix C - Contact sheets all photos of the investigation





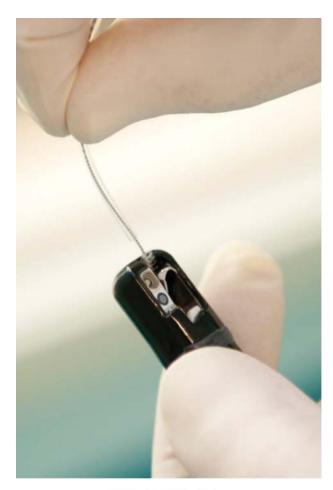
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D300s-ACL0004-eKL.jpg





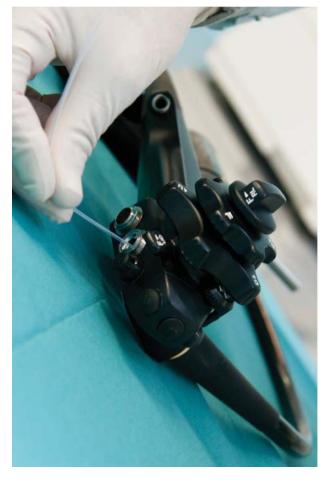
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D300s-ACL0009-eKL.jpg



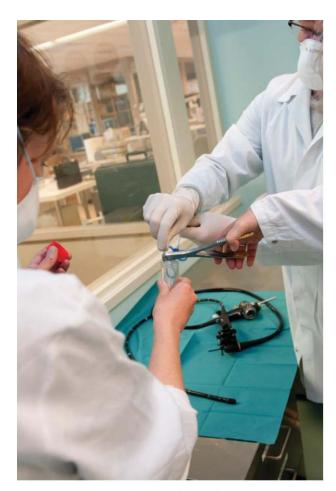
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D300s-ACL18-eKL.jpg





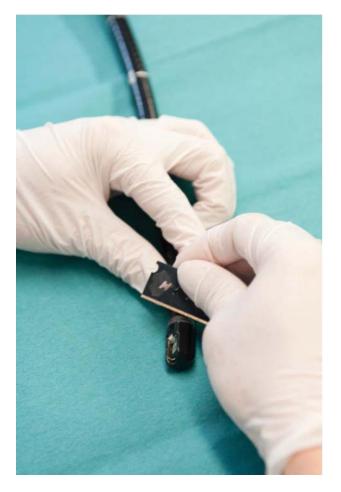
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D300s-ACL0020-eKLsq.jpg





D300s-ACL0024-eKL.jpg



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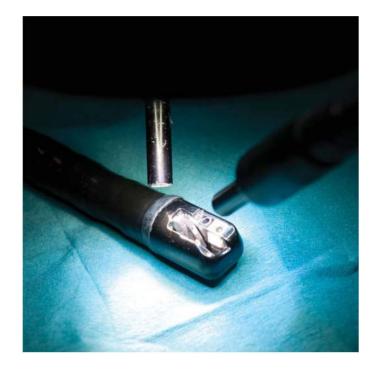
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D300s-ACL29-eKL.jpg



D300s-ACL0033-eKL.jpg



D300s-ACL0035-eKLsq.jpg





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D300s-ACL0040-eKL.jpg





D300s-ACL0043-eKL.jpg

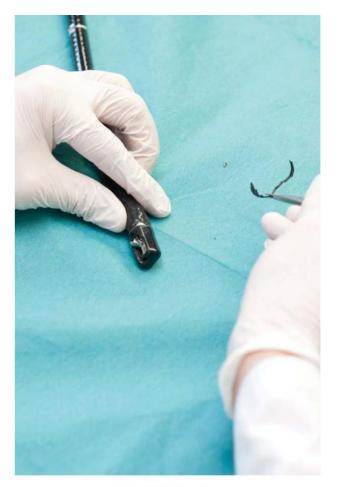


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erpakkings





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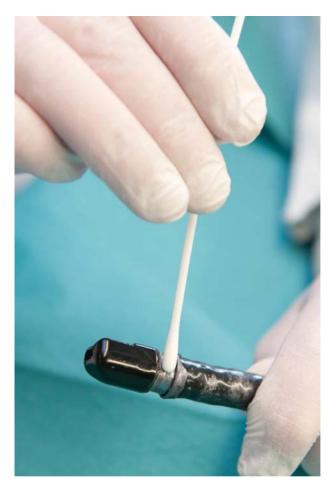
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D300s-ACL0053-eKL.jpg

D300s-ACL0052-eKLsq.jpg



D300s-ACL0054-eKL.jpg

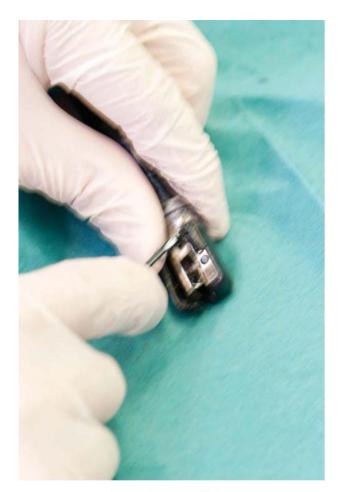


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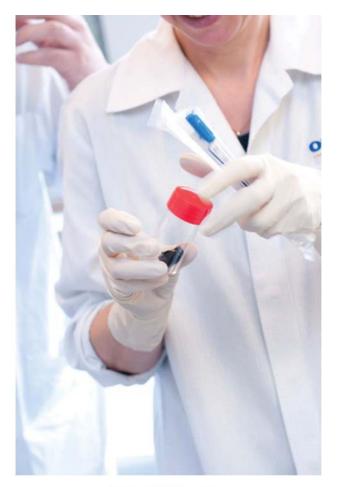




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D300s-ACL0061-eKL.jpg



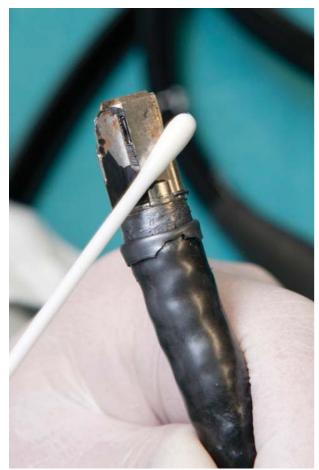
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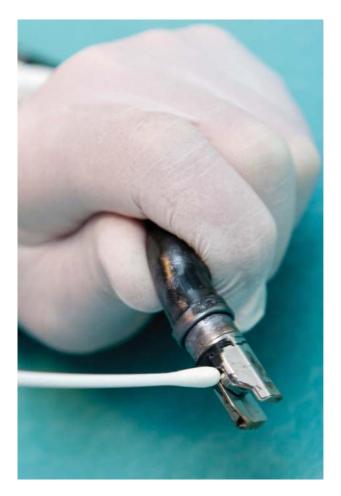


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D300s-ACL0069-eKL.jpg



D300s-ACL72-eKL.jpg

D300s-ACL0070-eKL.jpg



D300s-ACL0073-eKL.jpg



D300s-ACL0074-eKL.jpg





D300s-ACL0077-eKL.jpg

D300s-ACL79-eKL.jpg

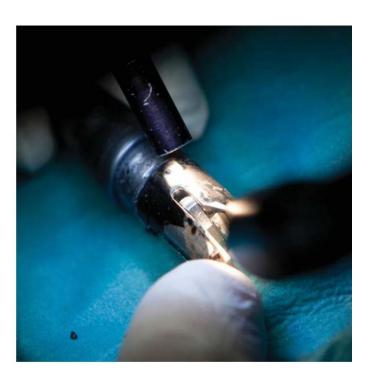


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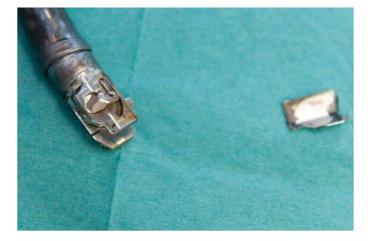
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D300s-ACL0083-eKL.jpg





D300s-ACL0086-eKL.jpg

D300s-ACL0090-eKL.jpg





D300s-ACL93-eKL.jpg



D300s-ACL0096-eKL.jpg



D300s-ACL0098-eKL.jpg



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D300s-ACL101-eKL.jpg



D300s-ACL0103-eKL.jpg





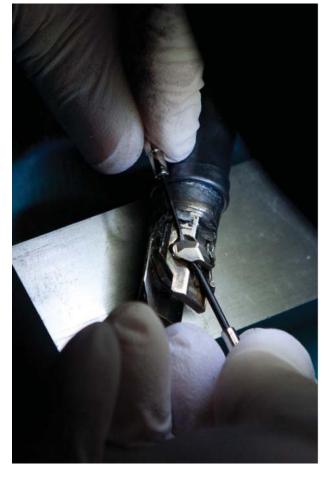
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D300s-ACL0113-eKL.jpg





D300s-ACL0107-eKL.jpg



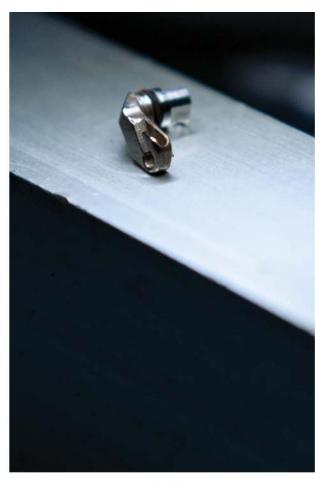
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D300s-ACL114-eKL.jpg

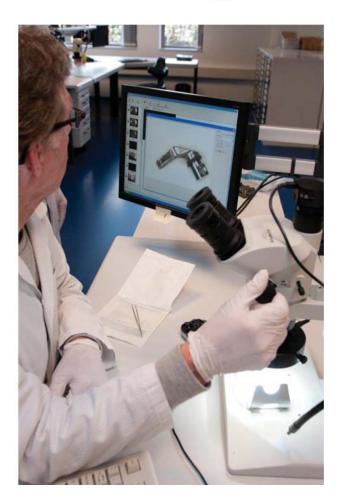


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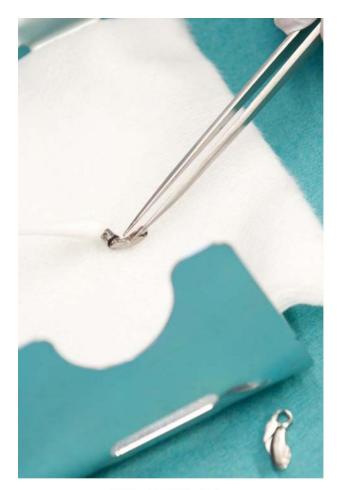
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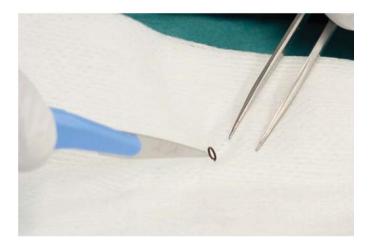


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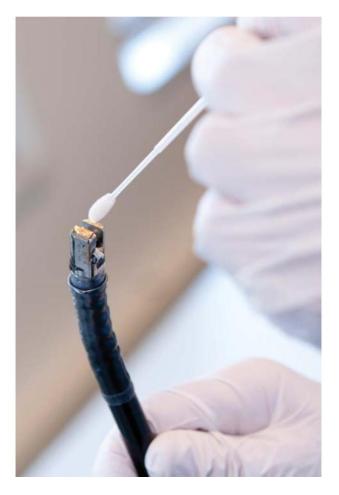




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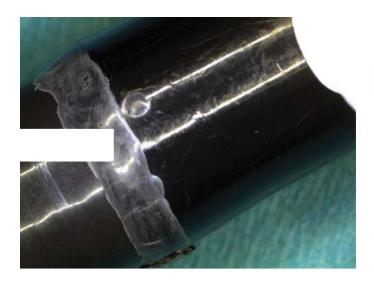


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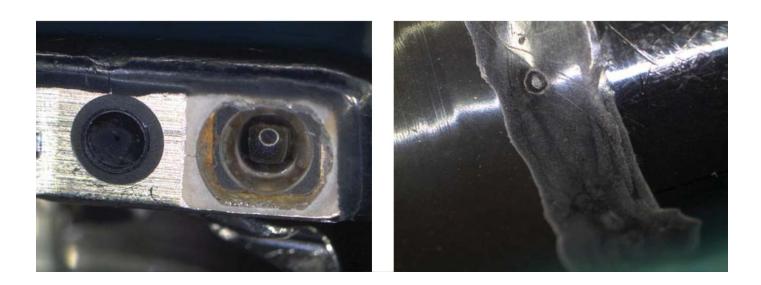
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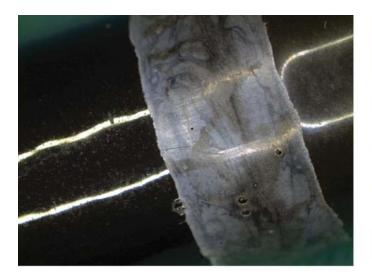


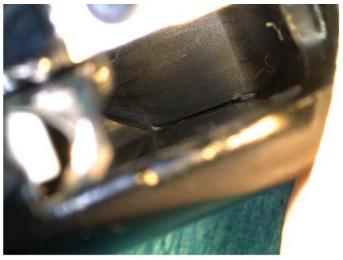


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Microsc-002.jpg

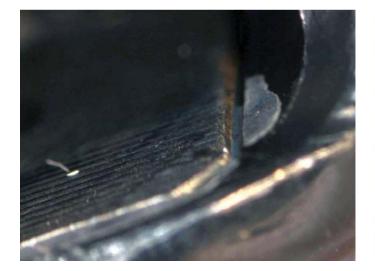


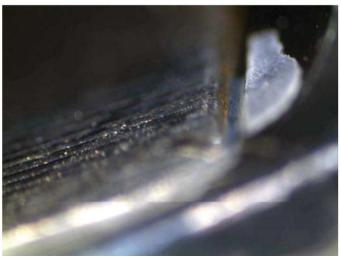


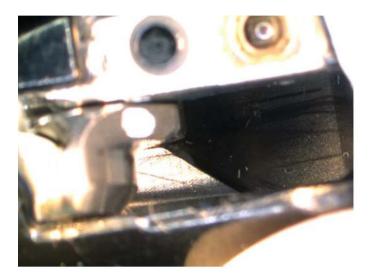


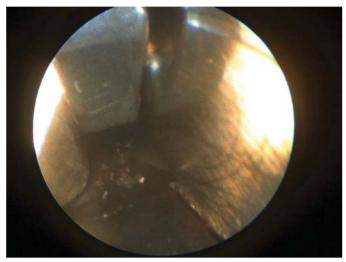
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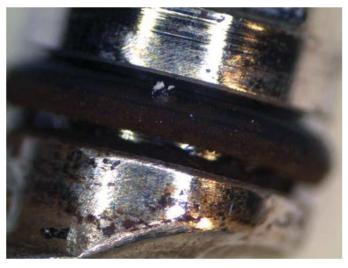
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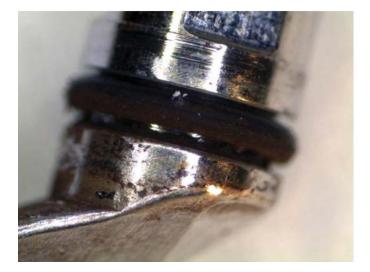


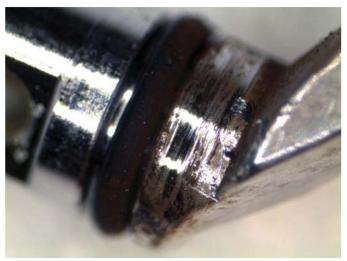




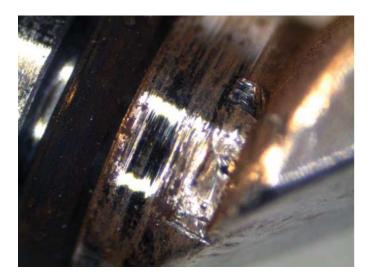
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Disinfection of Olympus TFJ-Q180V ERCP endoscope

Advice requested by: Advice formulated by: Verified by: Date of request: 22 October 2012 Date completed: 30 July 2013 Ad-hoc number: 2012-12 Project number: V/080118/01/AH

Ad-hoc request

The Healthcare Inspectorate (IGZ) asked the National Institute for Public Health and the Environment (RIVM) to give its opinion in connection with a report from the Erasmus Medical Centre (EMC) regarding problems when disinfecting the Olympus TFJ-Q180V flexible endoscope for endoscopic retrograde cholangiopancreaticography (ERCP).

Background

Following an outbreak of Verona integron-encoded metallo- β -lactamase (VIM) positive *Pseudomonas,* the EMC conducted an investigation into the possible sources of contamination. At the beginning of 2012, a source of contamination was found in the endoscope at hand, under the elevator. The endoscope was then taken out of service. By order of the EMC, the endoscope was subjected to a destructive examination by the TU Delft (Delft University of Technology) in April 2012, in the presence of representatives of the manufacturer and the hospital. The cap of the tip of the endoscope was opened. Samples were taken from inside the endoscope and examined for the presence of microorganisms. The resistant *Pseudomonas* stem was found in one place (sampling point 5478, denoted as "Cap").

The report on this investigation was sent to the manufacturer for comments and the manufacturer responded. As the conclusions of the report and the response from the manufacturer are contradictory, the IGZ was keen to get an opinion from the RIVM. In March 2013, a meeting was held between IGZ, EMC and RIVM to discuss and shed light on the problem.

RECOMMENDATIONS

The construction of the endoscope hinders optimum manual cleaning. The cap on the tip has been glued on so that it cannot be removed to brush clean the back of the elevator. The manufacturer acknowledges this and gives directions on how to rinse the back of the elevator with cleaning fluid during the (pre-)cleaning process and fixing the elevator in an open position before it is placed in the washer-disinfector. However, it is not evident from the information provided by the hospital that these details in the user manual were acknowledged and followed. It is not possible to establish the extent to which these two factors contributed towards the outbreak of *Pseudomonas*.

Although the manufacturer was asked expressly to provide information to show that the recommended cleaning procedure is effective, that the O-ring seal of the elevator is actually capable of preventing bacteria from getting into the endoscope and that the leak test, as user test or automatic test in the washer-disinfector, is accurate enough to establish the integrity of the O-ring seal, such information was not supplied.

Disinfection of the Olympus TFJ-Q180V flexible ERCP endoscope

Introduction

Endoscopes for endoscopic retrograde cholangiopancreaticography (ERCP) have a so-called elevator that is used to guide a device in the right direction from the endoscope's work channel to, for example, the bile duct. The elevator is served by a wire in the so-called elevator channel. It is usual for the elevator channel of an ERCP endoscope to be constructed in such a way that it is open on the patient side of the endoscope. This channel, just like the other channels in the endoscope, becomes dirty when the endoscope is used and has to be cleaned and disinfected before it is used again. The operating body of the endoscope is fitted with an access port along which the elevator channel can be flushed to clean and disinfect it internally. However, this is complicated by the fact that the channel is very narrow and is also largely filled with the wire that operates the elevator. Due to this narrow passageway, relatively high pressure has to be used, which still results in a very restricted flow.

The Olympus TFJ-Q180V endoscope in question is special, because the elevator channel is completely closed, so the inside of the channel does not, in principle, become contaminated during use and need not therefore be cleaned and disinfected. However, important questions which must be posed here are:

 $\cdot\,$ Is the construction of the seal at the tip effective enough to keep out even microscopically small contamination?

• Is it possible to clean and disinfect the external part (in this case the elevator) well? The EMC investigation also reveals that the construction of the tip makes effective cleaning difficult. For instance, the cap that covers the tip of the endoscope during use is glued on so that it cannot be removed to provide better access to the elevator below for brushing. EMC also makes use of other types of ERCP endoscope, the cap of which can be removed. No positive cultures were found with these endoscopes.

The report from the TU Delft and the manufacturer's response to this report led to further questions being posed to both the manufacturer and the hospital. The questions, the answers and our opinion can be found in annex 1 and annex 2 respectively. Also, on 18 March 2013, a visit was made to the EMC, where IGZ staff and the authors of this report discussed the matter with hospital representatives. A visit was also made to the cleaning and disinfection department.

Findings

1. In its response to the report from the TU Delft (see document 'Views on Report on Scope G-206' of 7 September 2012), the manufacturer emphatically draws attention to the cleaning instructions and repeatedly expresses doubts as to whether the hospital actually carried out the prescribed cleaning and disinfection procedures. From the information provided by the hospital, we can conclude that the manufacturer's cleaning instructions were partly followed by the hospital. The manufacturer's manual describes the manual cleaning of the endoscope. With respect to the elevator, Chapter 3 of the manual (pages 25-39) describes and illustrates with drawings how the elevator should be brushed. On page 45 of Chapter 3 it also states, independently of the other steps in cleaning the elevator, that the back of the elevator must be rinsed. This must be done by injecting cleaning fluid into the space behind the elevator by means of a syringe. A drawing of this has also been enclosed by way of illustration (see figure 1). The hospital stated that it followed the instructions described on pages 36-39 (see letter from the EMC to RIVM dated 29 March 2013).

2. The manufacturer also has available an abridged version of the cleaning instructions. This only mentions brushing the elevator, but not injecting the back. This document contains a clear warning that it is not complete and refers users to the user manual for full instructions. The status of the document is unclear.

3. With regard to mechanical cleaning, the manufacturer specifies that the endoscope must first be cleaned in accordance with the instructions in Chapter 3 of the manual. The manufacturer also states that one must check that the endoscope washer-disinfector is suitable for this endoscope. EMC uses Olympus ETD3 washer-disinfectors for the mechanical cleaning and disinfection. According to the manufacturer, these machines are

suitable for cleaning and disinfecting the TJF-Q180V endoscope. Finally, it is stated that the elevator must be fixed at an angle of 45° prior to mechanical cleaning and disinfection. This aspect is not mentioned in the hospital's work instructions for the mechanical cleaning of the endoscopes (document 'Disinfection of flexible endoscopes, Mechanical cleaning and disinfection in the disinfector').

Cleaning fluid Syringe Elevator Figure 1

4. The manufacturer provided a test report in which the validation of the manual cleaning and disinfection of the elevator is described (see Annex 1, point 8). However, the quality of the investigation left so much to be desired that it is not possible to support the conclusion drawn by the manufacturer, namely that the cleaning and disinfection procedure for the elevator is effective. Apparently, the manufacturer also failed to examine the efficacy of the procedure used by the hospital, consisting of a manual pre-clean followed by mechanical cleaning and disinfection. This procedure is the standard working method in the Netherlands, as prescribed by both the *Werkgroep Infectie Preventie* (WIP) and the *Stuurgroep Flexibele Endoscopen Reiniging en Disinfectie* (SFERD).

5. The manufacturer does not respond to the comments from the TU Delft examiner regarding the construction of the tip of the endoscope and the elevator which makes it impossible to brush the back and sides of the elevator effectively. The manufacturer refers to the previously mentioned validation report on the cleaning and disinfection.

6. Nor does the manufacturer discuss in a substantive way the comments made by TU Delft on the construction of the O-ring seal of the axis of the elevator. It is essential that this O-ring seal functions properly if contamination of the inside of the endoscope is to be prevented. During the meeting on 18 March 2013, the EMC technicians expressed their thoughts regarding the fact that no maintenance was prescribed for the O-ring.

7. The failure of the O-ring is mentioned in the manufacturer's risk analysis. As management measures, the manufacturer refers to durability tests which are carried out and the leak test that must be performed every time the endoscope is used. In the durability tests, the elevator is moved up and down a few thousand times, in stages, and a leak test is carried out after every stage in order to establish the integrity of the O-ring. However, three factors are not taken into account in the durability tests. Firstly, the overpressure to which the endoscope is exposed during normal use and which can aid the ingress of contamination along the O-ring. Secondly, the endoscope is not cleaned and disinfected during the test. It cannot be ruled out that the O-ring is adversely affected by the cleaning and disinfection process and deteriorates in quality as a result. This is analogous to the damage caused to rubber parts in the ETD3 washer-disinfector in the course of time. It is possible that this results, in practice, in a shorter life span than can be assumed on the basis of the durability tests. Thirdly, there is the time factor. O-rings age, so their elasticity decreases in the course of time.

8. All in all, the manufacturer states that the leak test is <u>the</u> method by means of which the user must determine the integrity of the O-ring seal, based on the assumption that the O-ring is in order if the leak test is satisfactory. The manufacturer does not give a substantive answer to our question regarding the degree of evidence that the leak test is suitable for demonstrating that the O-ring seal is tight enough to keep out bacteria too. The manufacturer adopts the stance that air molecules are smaller than bacteria and, consequently, that bacteria cannot pass through if there is no air leak. There are two arguments against this. Firstly, the manufacturer is ignoring the fact that the leakage of air only becomes visible to the user when the air bubbles have reached a certain size and that not every leak will therefore be visible in the leak test. Also, the leak test in the washer-disinfector is conducted as an instrumental method, whereby the absence/presence of leaks is checked on the basis of the fall in pressure in the endoscope in a certain period. The manufacturer of the endoscope must state what fall in pressure can be considered acceptable. The manufacturer fails to do this, however. Secondly, the end of the endoscope must be moved (so-called wagging) during the leak test, in

accordance with the manufacturer's instructions. This makes it easier to see any small cracks in the cardan rubber. Analogous to this, it is advisable with the endoscope in question to move the elevator up and down during the leak test. As a result, the interfaces between the axis of the elevator and the O-ring will move in relation to one another and possible leakages will be more easily visible as a result. The endoscope manual provides no instructions about this, however.

9. During the examination of the endoscope by the TU Delft, corrosion was observed on the internal parts of the endoscope. However, this does not necessarily mean that the O-ring in the seal of the elevator functioned badly and contributed towards the infections with VIM positive *Pseudomonas*. This is because the maintenance history of the endoscope reveals that the endoscope had been repaired twice due to a leaking cardan rubber. It cannot be ruled out that fluid penetrated the endoscope during these leakages, resulting in the observed corrosion of the metal parts.

Conclusions - general

The construction of the endoscope hinders optimum manual cleaning. The cap on the tip has been glued on and cannot therefore be removed to brush clean the back of the elevator. The manufacturer acknowledges this and provides instructions for rinsing the back of the elevator with cleaning fluid during cleaning and for fixing the elevator in an open position before it is placed in the washer-disinfector. It was not evident from the information provided by the hospital that these instructions had been followed. It is not possible to establish to what extent the two factors (limitations in the design and the failure to follow fully the cleaning instructions) contributed towards the outbreak of VIM positive *Pseudomonas*.

Patients who undergo an ERCP always run the risk of becoming infected with *Pseudomonas*. From the information provided by the hospital, it is evident that, in a certain period, 36 patients were found to have a *Pseudomonas* infection. 22 of these patients had been treated with the TJF-Q180V endoscope.

Conclusions – with respect to the construction of the endoscope

The construction of the endoscope in question deviates in a number of ways from the 'conventional' ERCP endoscopes (see introduction). An O-ring seal, in principle, prevents contamination of the elevator channel, so it is no longer necessary to clean and disinfect this channel. With this construction, the integrity of the O-ring is of vital importance. If the O-ring leaks, the inside of the endoscope becomes contaminated and the (cross-)infection of patients cannot be ruled out. The manufacturer must therefore investigate if his design does actually provide an adequate seal. The manufacturer was asked for the validation data on the O-ring construction. These were not supplied, so we must conclude that the construction has not been validated in terms of keeping bacteria out. The durability test carried out does not provide an alternative to this. In addition, it must be possible for the user to check the integrity of the seal. The manufacturer assumes that the leak test as conducted by the user provides enough guarantees for this, but has not investigated this. It has not been established, namely, that the leak test would detect a leak along the Oring large enough to let bacteria through. In addition, the leak test is conducted statically, in accordance with instructions, whereas it is better, for technical reasons, to move the elevator when carrying out the leak test.

During the destructive examination of the endoscope, brown discolouration was observed on the inside. However, it cannot be concluded from this that the O-ring seal had failed, as was suggested by the examiners, because the maintenance history of the endoscope reveals that the endoscope had been repaired twice due to leakage. It is therefore also possible that the observed corrosion resulted from this.

A second detail of the construction is the glued-on cap on the tip of the endoscope. As this cap cannot be removed, it is not really possible to brush the back of the elevator clean. The manufacturer takes account of this in the user manual by stating that the back of the elevator must be rinsed during manual cleaning and that the elevator must be fixed at an angle of 45° before it is placed in the washer-disinfector.

Conclusions – with respect to the cleaning procedure followed

The hospital partly followed the manufacturer's instructions when cleaning and disinfecting the endoscope. The endoscope was cleaned and disinfected mechanically in an Olympus

ETD3 washer-disinfector, which the manufacturer considers suitable for the endoscope in question. Before the endoscope was placed in the washer-disinfector, it was cleaned manually. In doing so, the hospital did not follow all the instructions in the user manual. The elevator was brushed, but the second step, flushing the back of the elevator with cleaning solution, was not carried out. There were no specific instructions in the protocol received that the elevator had to be fixed at an angle of 45° before the endoscope was placed in the washer-disinfector.

As part of the manual pre-clean, a leak test was conducted. The elevator was not moved up and down during this test. Nor does the manufacturer prescribe this. Annex 1: Manufacturer's response to RIVM questions

This Annex is in English to facilitate the communication with the manufacturer. The response of the manufacturer to the report of TU Delft was studied by RIVM. On a number of issues clarification was asked from the manufacturer. The RIVM comments, the responses from the manufacturer and the evaluation of those responses are given below.

1. Comment RIVM: The elevator channel is of a different design than that in other endoscopes for ERCP. Normally the elevator channel is open at the tip, which allows the ingress of contamination during use in the patient. To remove the contamination from the inside of the elevator channel it is fitted with an entry port that allows flushing with detergent and disinfectant. The elevator channel of the TJF-Q180V endoscope is sealed, probably with the intention to prevent contamination of the inside of the channel. The precleaning instructions that we retrieved from the internet clearly state: "The sealed forceps elevator wire of the TJFQ180V means that the elevator wire channel does not require flushing and rinsing." It is unclear at this moment whether flushing the channel is at all possible, although not required. If it is not possible to flush the channel, this means that the inside cannot be decontaminated, even when the seal of the channel fails and the inside of the channel becomes inadvertently contaminated.

The manufacturer responded by stating that sealed cavities do not need to be reprocessed as they cannot be contaminated as long as the endoscope is in perfect condition. The manufacturer states that the latter can be verified by performing the leakage test as part of each reprocessing procedure.

The manufacturer describes that the leakage test is performed by raising the internal pressure

in the endoscope to 'approx. 30 kPa'. The manufacturer suggests that this should be sufficient as the external pressure during clinical use is only 3 kPa.

Evaluation

The manufacturer does however not consider:

- That during use in the patient the elevator is raised and lowered, which causes the seal to be challenged under dynamic conditions, when rotational forces and axial forces are applied, which may aid the ingress of contaminants past the seal,

- The fact that during leakage testing the pressure to the seal is applied from the opposite side compared to the use situation. The test may not be suitable for all possible seal failure modes.

2. RIVM request: The risk analyses for the TJF-Q180V endoscope, especially the risk analyses of the possible failure modes of the seals in relation to the consequent contamination of the elevator channel and subsequent cross infection between patients. The manufacture has provided a part of the risk analysis in which he recognizes three hazards:

- A water seal gets damaged during a procedure, and contaminants invade into the device. A reprocessing operator does not notice the leak, the device is used in the next procedure, and it results in patient infection.

- A water seal gets damaged due to the broken O-ring during a procedure, and contaminants invade into the device. A reprocessing operator does not notice the leak, etc.

- A water seal gets damaged due to the broken O-ring during a procedure, and contaminants invade into the device. A bubble did not emerge during the leak test, etc. These hazards are mitigated by the instruction to the user to perform a leakage test as described in the user manual.

Evaluation

Two documents containing reprocessing instructions could be retrieved from the internet. The first document is a single sheet, titled 'Pre-cleaning your TJF-Q180V'. This instruction sheet, albeit in a different format, has also been sent to the users of the TJF-Q180V endoscope in the Netherlands, as part of the Field Safety Notice of January 2013. The sheet does not mention the performance of a leak test.

The second 14 page document is titled 'OnTrack Reprocessing In-Service/Competency for JF/TJF Endoscopes'. The instructions state that a, non-specified, leakage tester should be connected to the endoscope and the endoscope should be inflated. The inflated endoscope should be immersed in water completely. The user should 'observe' for 30 seconds while

angulation the bending section. No instruction is given to raise and lower the elevator, which means that the elevator axle seal is only challenged under static conditions, rather than the more realistic dynamic conditions. See also response to point 6 regarding the use of automated procedures in the Netherlands.

The IFU of the endoscope prescribes that the distal end of the endoscope shall be moved during leak testing. It is however not prescribed that the elevator shall be raised and lowered to ensure that the O-ring seal is challenged under dynamic conditions.

3. RIVM request: The validation of the design of the seals of the elevator wire channel; the establishment of the mean time between failures of the seals and how this impacts the maintenance schedule for this type of endoscope.

The manufacture states that the mean time between failures is not established. Failure of the seal should be detected during leakage testing.

Data are provided that show that the performed durability test in which the elevator is repeatedly raised (up to 18000 times) gives no detectable leakage.

Evaluation

The manufacturer again presumes that the leakage test can demonstrate the capability of the elevator axle seal to prevent the ingress of contamination. However, no information has been provided that demonstrates that this presumption is valid. Moreover, the durability tests have not been performed under actual use conditions. The presence of body fluids and contamination during the operation of the endoscope, the subsequent cleaning and disinfection and general ageing could influence the outcome of the durability testing.

4. RIVM request: The validation of the design of the seals of the elevator wire channel; the ability of the seal to prevent the ingress of bacteria into the sealed area under movement of the elevator lever, both in radial and axial direction, for the duration of the planned maintenance interval or the expected number of uses of the endoscope.

Evaluation

The manufacturer has not responded to this request.

5. RIVM request: Validity of the leakage test; The data that demonstrates that a leak in the seals on a microscopic level, that is a leak that is very small, but nevertheless allows the passage of bacteria into the sealed area of the scope and back, will be detected by leak testing as described in the user manual. The leak test has been identified as an important, and apparent only, mitigation to the risks of a leaking seal in the endoscope (see 2). The leak test is also used as the pass/fail criterion in the durability study (see 3). It should therefore be demonstrated that the leak test is actually suitable to detect failures of the seal that will allow the ingress of microorganisms into the endoscope during use. The manufacturer responded by pointing out that air molecules are smaller than bacteria. "Therefore, if the air cannot pass through the seal, the bacteria can also not penetrate the seal."

Evaluation

The leakage test procedure described by the manufacturer relies on visual observation by the person performing the test. No information has been provided to demonstrate that a leakage that will allow the passing of bacteria will be detectable by visual observation. Visibility also depends on the abilities of the observer.

The manufacturer should provide information that demonstrates this principle, because the formation of visible air bubbles does depend on several factors such as surface tension of the liquid and leak rate.

6. RIVM request: Validity of the leakage test; the allowable leak for this type of endoscope when tested in accordance with the instructions of the manufacturer.

Evaluation

The leakage test procedure prescribed by the manufacturer is a manual procedure that relies on the visual observation by the person performing the test. However, in the Netherlands it is common that the leakage test is performed in the washer-disinfector as part of the automatic reprocessing procedure. The washer-disinfector shall give an alarm when during the automatic leak test the pressure in the endoscope drops more than is

allowed. According to ISO 15883-4 (standard for washer-disinfectors for flexible endoscopes) the allowed pressure drop shall be specified by the manufacturer of the endoscope. It is this information that we requested, but did not receive.

7. RIVM request: Validity of the leakage test; construction drawings of the endoscope indicating the parts of the endoscope that are pressurized during leak testing.

Evaluation

This information was not received, but we understand that entire inner volume of the endoscope is pressurized so that all seals are challenged, including the elevator axle seal.

8. RIVM request: The data that demonstrate that the areas of the elevator and its surroundings as identified by EMC are effectively cleaned and disinfected applying the reprocessing instructions that are provided by Olympus. The EMC gave comments on the design of the elevator. The design of the elevator does not facilitate the cleaning of the back of the elevator and the sides of the elevator. The EMC also commented that the tip of the endoscope has several cracks, corners and cavities which could not or only with great difficulty be reached with a cytology brush for sampling. They specifically mention: "The following areas in particular proved difficult to reach for this brush: - the crack under the hinge point of the elevator, - the crack caused by the axial play of the elevator, - the space below/behind the curve of the elevator.".

The aforementioned instructions for pre-cleaning prescribe that the front and the back of the elevator shall be brushed, but given the difficulty EMC experienced in sampling these positions one may question the validity of the brushing instructions.

The manufacturer provided the test report "Cleaning and Disinfection efficacy in TJFQ180V", for the manual cleaning and disinfection procedure. The results from this study were included in the information that was received earlier, but is now complete including the method used. The test has been performed in June and July of 2008, the report is signed however on January 21, 2013.

Evaluation

The study is unacceptable as a demonstration of effective cleaning, because it has the following flaws:

- In the test only the manual cleaning and disinfection is evaluated, not the automated procedure in an ETD3 washer-disinfector.

- ISO 15883-5 gives in annex I a method to evaluate the combined efficacy of the cleaning and disinfection process of a flexible endoscope. The required total reduction factor of the test organism should be at least log 9. This is considerable higher than the 4 log reduction that the manufacturer regards to be sufficient.

- The pass criteria are copied from EN14563:2008, that is the European standard for the in-vitro testing of disinfectants against mycobacteria. The standard requires that the efficacy in the test shall be at least 4 lg. This reduction factor has only meaning for the in-vitro test method and has no bearing on the required reduction in the practice of endoscope reprocessing.

- In clause 2 the manufacturer mentions that the cleaning and disinfection will be performed on seven test devices (samples) and will not be performed on five other test devices (controls). The results are only shown for five samples and two controls.

- In 7-2 (1) the manufacturer describes the use of a suspension of microorganisms. The composition of the suspension is not prescribed. Since the complete process, cleaning plus disinfection is evaluated the suspension should also provide a challenge to the cleaning process. Annex G of ISO15883-4 indicates that the number of microorganisms that is left on the device after the cleaning should be established to ensure that sufficient microorganisms are present to present a challenge to the disinfection stage of the process. This has not been done.

- 7-2 (4) typo, 200 ml instead of 200 $\mu l.$

- In 7-2 (6) the manufacturer describes that the inoculated elevator shall be left for 30 minutes at room temperature to fix the microorganisms to the test instrument. No data have been provided to demonstrate that the microorganisms are indeed fixed.

- 7-3 and 7-4 cleaning/disinfection of the elevator wire, despite the fact that this wire is sealed in this endoscope type. This raises the question whether the test has actually been performed on a TFJ-Q180V endoscope.

- From 7-5 (1) we learn that the residual contamination that is present after the process shall be transferred into 200 ml of extraction fluid. Starting with an initial

contamination of 600 μ l the dilution into 200 ml gives an additional reduction of approx. 2.5 log. It is unclear whether the test results have been corrected for this. - 7-5 (3) the method of incubation of the extraction fluid is not specified; spread plate or filtration.

Annex 2: EMC response to questions from RIVM

In its initial reaction to the report from TU Delft, the manufacturer places a strong emphasis on the importance of following the correct cleaning and disinfection procedure. In order to find out if the hospital possibly fell short in this respect, IGZ was asked to request additional information from the hospital. This never happened, however. During the meeting on 18 March, the authors of this report requested the information orally. On 29 March, further details of the information obtained orally were provided by e-mail. It concerns the following:

1. The details of the previous investigation conducted by the EMC, whereby the bacterium *Pseudomonas aeruginosa* was found in the tip of the endoscope. We would like to know the precise location on/in the endoscope where the bacterium was found and how the samples were taken.

Response from EMC: the contamination was found on the back of the elevator in the narrow passage between the back of the elevator and the bottom of the endoscope tip. The sampling was not simple and is described as follows by EMC: "A culture was made of the underside of the elevator in a sterile environment. First of all, the elevator in question was moistened with sterile water. Then a number of fibres were removed from a sterile cotton swab using sterile tweezers. These fibres were pushed under the space behind the elevator with the aid of the tweezers and moved backwards and forwards. The fibres were then deposited in a sterile container and cultured."

The hospital also stated that the bacterium persisted following manual pre-cleaning and mechanical processing. We would like to see the details of the manual precleaning, in particular which parts of the tip of the endoscope were cleaned during this process and how this was done.

EMC stated that the manual pre-cleaning took place in accordance with the manufacturer's manual, pages 36-39. This section of the manual describes brushing the elevator.

NB: Apparently, the hospital does not flush the back of the elevator as described on page 45 of the manual. This is an important step, however, because it is difficult for the brush to reach the back of the elevator.

2. The instructions for cleaning and disinfecting the Olympus TJF-Q180V endoscope as supplied with the endoscope.

EMC enclosed a copy of the manual for the endoscope.

3. The work instructions for cleaning and disinfecting this endoscope as applied by the EMC.

Response from EMC: See 1, second point. The use of the endoscope washer-disinfector is described in the protocol 'Disinfection of flexible endoscopes, Mechanical cleaning and disinfection in the

disinfector.' This does not state that the elevator must be fixed at an angle of 45° before being placed in the washer-disinfector.

During the guided tour of the department, we came across brief work instructions. There were none for the endoscope in question. These had possibly existed but had been removed because the scope was no longer in use. Nor is it possible to trace the work instructions, as the brief work instructions are produced by the departmental staff themselves and are not controlled documents.

4. Possible work instructions applied by EMC when carrying out a manual leak test.

Response from EMC: the execution of the leak test is described in the protocol 'Disinfection of flexible endoscopes, Leak tests on the endoscope' and is carried out in accordance with the manufacturer's instructions. The distal end of the endoscope is 'wagged' here, but the elevator is not moved up and down.

- 5. The following details of the endoscope washer-disinfectors in which this endoscope was cleaned and disinfected, in particular:
 - a. brand and type
 - b. the washing process, name of detergent, concentration and temperature

c. the disinfection process, name of disinfectant, concentration and temperature d. details of the leak test performed by the washer-disinfector, in particular the size of the leakage permitted.

Response from EMC: The hospital uses the ETD3 washer-disinfectors to clean and disinfect all endoscopes. The specifications of the leak test performed by the washer-disinfector were not known. The manufacturer does not state that this leak test would have been unsuitable for the endoscope in question.

6. A copy from the list of endoscopes which the manufacturer of the washerdisinfector states can be cleaned and disinfected effectively, from which it appears that the TJFQ180V is on the list.

From RIVM archives: the document 'Adapters for ETD3 - Compatibilities' version 08/2011 names the adapters needed to connect the TJF-Q180V endoscope in the ETD3 washer-disinfector. This implies that the endoscope can be cleaned and disinfected effectively in the washer-disinfector.

National Institute for Public Health and the Environment Ministry of Health, Welfare and Sport

Advice centre for medical devices and consumer products e-mail:

Disinfection of Olympus TFJ-Q180V ERCP endoscope Response from Erasmus MC

Advice requested by: Advice formulated by: Verified by: Date of request: 10 September 2012 Date completed: 14 October 2013 Ad-hoc number: 2013-06 Project number: V/080118/01/AH

Ad-hoc request

The Healthcare Inspectorate (IGZ) asks for comments on the letter dated 10 September 2013 from Doctor B.J. Smit regarding his response to the National Institute for Public Health and the Environment's (RIVM) recommendations on disinfecting the Olympus TFJ-Q180V flexible endoscope (ad-hoc request 2012-12), by 15 October at the latest.

Background

The IGZ asked the RIVM to pass judgement in connection with a report from the Erasmus Medical Centre regarding the problems when disinfecting the Olympus TFJ-Q180V flexible endoscope for endoscopic retrograde cholangiopancreaticography (ERCP). The IGZ sent the recommendations drawn up by the RIVM (ad-hoc request 2012-12) to the Erasmus MC on 2 August 2013. The Erasmus MC sent a letter to the IGZ on the matter on 10 September 2013.

RECOMMENDATIONS

In these recommendations, the comments from the Erasmus MC on our earlier advice concerning the problems when disinfecting the Olympus TFJ-Q180V flexible endoscope (ad-hoc number 2012-12), as expressed in the letter with reference DPZ-10686 of 10 September 2013, are addressed point by point.

Disinfection of the Olympus TFJ-Q180V flexible ERCP endoscope. Response from the RIVM to the letter from Erasmus MC dated 10-09-2013, reference DPZ-10686

From the letter from Erasmus MC dated 10 September 2013: Conclusion

On the basis of the report from the National Institute for Public Health and the Environment (RIVM), we conclude that this involves a medical instrument of dubious construction, which has not yet undergone all the necessary validation studies and which comes with cleaning and testing instructions for which the same applies. Insofar as we can judge, this means that the medical instrument in question does not comply with the basic/essential requirements as referred to in the Medical Device Directive (MEDDEV) and so should not be used in a clinical setting. In fact, the RIVM report contains all the necessary information to support this conclusion. We trust that the Healthcare Inspectorate (IGZ) extracts and acknowledges the same message from the report. It would make things a lot clearer if the RIVM and the IGZ were to actually put this conclusion into words. The Erasmus MC has a great need for a concrete conclusion or recommendation from IGZ and RIVM as to whether or not the TJF-Q180V can be used safely when treating patients at the Erasmus MC.

<u>Response from RIVM</u>: Here, Erasmus MC presents its interpretation of the contents of our report. We leave it up to IGZ to respond to this as necessary.

From the letter from Erasmus MC dated 10 September 2013: Factual inaccuracies/ other comments

General comment: please replace EMC with Erasmus MC

<u>Response from RIVM</u>: It is our custom to write a frequently used term in full the first time followed immediately by the abbreviation we will subsequently use in brackets; see p.1 under 'Ad-hoc request'. In any future reports, we will write "Erasmus MC".

Recommendation on page 1: in our opinion, this block does not contain any advice, but
a summary of the findings. It is incorrectly stated that the Erasmus MC failed to
acknowledge and follow the instructions in the user manual.

<u>Response from RIVM</u>: We must take the information provided by the hospital as our basis; this is also how we expressed the finding. It was noted that a number of specific directions from the manufacturer of the TJFQ180V endoscope were missing from the work instructions provided by the hospital for cleaning and disinfecting flexible endoscopes. No specific work instructions were received for the endoscope in question.

 Page 3, finding 1: It is stated that the instructions were only partially followed. This is incorrect in our opinion. We always complied with the complete user manual (IFU).

<u>Response from RIVM</u>: It was noted that a number of specific instructions from the manufacturer of the TJFQ180V endoscope were missing from the work instructions provided by the hospital for cleaning and disinfecting flexible endoscopes. No specific work instructions were received for the endoscope in question.

• Page 3, finding 2: The field safety warning (brief guide) from Olympus dated January 2013 was not applied by the Erasmus MC, as the scope had already been out of service since March 2012. The full user instructions were available in the department.

<u>Response from RIVM</u>: As stated in the report, the complete user manual is decisive here.

• Page 4, finding 3: It is said of 'the work instructions from the hospital' (document Disinfection of flexible endoscopes, Mechanical cleaning and disinfecting in the disinfector) that these are a general protocol and not a specific protocol for the TJF-Q180V.

<u>Response from RIVM</u>: During the conversation with Erasmus MC, specific work instructions for the Olympus TJF-Q180V endoscope were discussed. These proved not to be available, however. It was said at the time that these work instructions had possibly existed, but had been removed after the endoscope was taken out of service. It was not certain if specific work instructions had ever existed. It was said that such specific work instructions were not a controlled document, but drawn up by the member of staff charged with cleaning and disinfecting the endoscopes him or herself. In our opinion, such work instructions should be a controlled document within a good quality system. The RIVM received no work instructions to

show that the specific directions from the manufacturer were acknowledged and followed; we base our finding on this.

3

 Page 4, finding 3: You state that the work instructions 'Disinfection of flexible endoscopes, Mechanical cleaning and disinfection in the disinfector' do not describe fixing the elevator at an angle of 45° prior to mechanical cleaning and disinfection. An objective fact is that, considering the construction of the elevator, it cannot be fixed as can e.g. the large and small switch. The elevator is fixed in such a way (in a closed position) that the area behind it can be cleaned and disinfected mechanically as well as possible. We suggest removing this sentence.

<u>Response from RIVM</u>: No work instructions were provided which contained directions on how to position the elevator at an angle of 45° or in any other way prior to the endoscope being placed in the washer-disinfector. When Erasmus MC realised that the manufacturer's instructions could not be followed, they should have discussed this with the supplier. It is apparent from the information provided that no such feedback was provided. For the time being, we therefore assume that the instructions, as described above by Erasmus MC (fixing the elevator in a closed position), was not mentioned earlier. Restraint must always be shown when modifying the user manual according to one's own judgement. In the case in question, fixing the elevator in a closed position could perhaps result in a diminished flow through the biopsy channel and hence in less effective cleaning and disinfection.

• Page 4, finding 6: It says here: 'Nor does the manufacturer discuss in a substantive way the comments made by TU Delft on the construction of the O-ring seal' whilst the findings from the extensive technical investigation, including photographic evidence, show that there is a significant problem here, with potentially major consequences for patient safety.

Response from RIVM: correct.

• Page 4, finding 7: The fact that Olympus referred to the failure of the O-ring in the risk analysis creates obligations. Olympus should take additional measures itself in accordance with the MEDDEV to prevent this "fault condition". It is now quite wrongly left solely to the user to take control measures (leak test) and, alongside the meagre underpinning of the control measure, Olympus also fails here to provide a substantive response to the issue of keeping out bacteria.

<u>Response from RIVM</u>: According to the Medical Device Directive (MEDDEV), Annex I, I.2, the manufacturer is obliged to eliminate or reduce risks as much as possible, with the solution first being sought in the design ("inherently safe design and construction"). If this is impossible or not sufficiently possible, the MEDDEV gives the manufacturer the option of taking other measures (e.g. providing the user with specific instructions to carry out checks).

Page 5, conclusions regarding the construction: We have a problem with how the RIVM formulates its views on finding the brownish deposit on the inside of the mechanism in the tip. The RIVM stresses emphatically that this was not necessarily caused by a leak, but fails to repeat that this is definitely one of the possibilities. This last possibility has potentially major consequences for patient safety and thus for the use of the equipment. Due to this safety issue, we believe that the explanation that a leak is the cause of the deposit takes precedence over an alternative, more innocent explanation, unless this possibility can be rejected with a probability bordering on certainty by means of a thorough investigation and analysis.
 All of this must be seen in the light of the proven causal role of the scope in question in the transmission of the *Pseudomonas aeruginosa* bacterium (of the clonal type). Also, the idea is created that the researchers made a one-sided suggestion on the matter, which is certainly not the case. We request that you qualify this.

<u>Response from RIVM</u>: The RIVM report looks at the considerations concerning the O-ring construction and the way in which the condition of the O-ring should be checked for use. In the report from the TU Delft, the brown deposit is discussed and the only possible cause given is that the O-ring leaked.

However, the RIVM noted that there was also another possible cause, i.e. a leaking cardan rubber. For reasons of meticulousness, this was included in the RIVM assessment. The reason for the corrosion cannot be established with any certainty.

• Page 11, point 1: This concerns the scope that came out of the disinfector and had therefore undergone the complete manual and mechanical cleaning and disinfection process.

Response from RIVM: correct.

• Page 11, point 3. It is true that work instructions for the endoscope in question were no longer available, as this type of scope had been held in quarantine for more than a year at the time of your visit to the MDL endoscopy department of the Erasmus MC. The work instructions had been removed to avoid confusion.

<u>Response from RIVM</u>: See Page 4, finding 3 above.

Appendix III: Communications from Olympus to Customers in Europe

The following are letters sent by Olympus to customers in Europe.

January 2013

Important Safety Advice

Safe reprocessing of TJF-Q180V

Dear Olympus Customer

With view to a recently reported case of a contaminated Olympus Video-Duodenoscope TJF-Q180V, we would like to draw your enhanced attention to the following points:

- Closely observe all instructions from the reprocessing manual for TJF-Q180V
- Pay particular attention to the detailed pre-cleaning instructions, especially for the distal end and forceps elevator

For your review, please find enclosed a paper safe for quick reference. It should be regarded as additional information to the reprocessing instructions from the manual.

In addition to the above mentioned points, we would also like to remind you that TJF-Q180V, as all Olympus endoscopes, has to undergo detailed preparation and inspection before patient use. In case you observe any damages or irregularities, do not use the endoscope and contact Olympus for inspection and repair. Using an endoscope that is not functioning properly may compromise patient or operator safety and may result in more severe equipment damage.

For further information on the required steps, please refer to Chapter 3 "Preparation and Inspection" of the instruction manual of TJF-Q180V. Additional copies of the instruction manual or the above mentioned reprocessing manual are available at any time upon request.

We trust the enclosed information will prove helpful, but if you have any questions or would like to receive additional training on any aspect of the care and maintenance of your Olympus TJF-Q180V, please contact your local Olympus representative who will be delighted to make the necessary arrangements.

Yours sincerely,

REPLY FORM

Olympus Subsidiary/Distributor	
[Dept/Attn]	
[Street No.]	
[ZIP City]	
	Date
	Ref No.
	EXT-xxx
Important Safety Advice: Safe reprocessing of TJF-Q180V	

Dear Sirs and Madams,

We herewith confirm the receipt of your customer letter. We will share this information with the relevant departments.

Name	
Hospital	
Department	
Street	
Postal Code/ City	



TJF TYPE Q180V

Medical Endoscopy

Pre-cleaning your TJF-Q180

The TJF-Q180V has a number of features enabling easier reprocessing. This quick reference guide provides an overview of the main improvements to the pre-cleaning procedure.

At the light source:

The distal cap of the TJF-Q180V is fixed and is therefore not removed prior to pre-cleaning

The sealed froceps elevator wire of the TJF-Q180V means that the elevator wire channel does not require flushing and rinsing



3

During manual cleaning:

Before automated reprocessing:

Use one of the recommended brushes to brush the front and rear side of the forceps elevator

The MAJ-1888 brush can be used for heavy soiling or delayed reprocessing situations and enables deeper access to the forceps elevator

The sealed forceps elevator wire of the TJF-Q180V means that the elevator wire channel does not require flushing and rinsing









Set and lock the forceps elevator to 45° before placing the endoscope into an automated washer disinfector to enable cleaning and disinfection of both sides of the forceps elevator

This sheet is for quick reference only. For detailed reprocessing instructions, please refer to the TJF-Q180V reprocessing manual.

Specifications, design and accessories are subject to change without any notice or obligation on the part of the manufacturer.



OLYMPUS EUROPA HOLDING GMBH

Postbox 10 49 08, 20034 Hamburg, Germany Wendenstrasse 14–18, 20097 Hamburg, Germany Phone: +49 (0)40 237 730, Fax: +49 (0)40 230 761 www.olympus-europa.com

QIL 145-006, 07.01.13

May X, 2014

URGENT: Field Safety Corrective Action

Attention:

Re: EVIS EXERA II DUODENOVIDEOSCOPE TJF-Q180V

Dear Customer,

Recently Olympus has received a few complaints of residual debris in the distal end of the TJF Q180V duodenoscope after reprocessing. Olympus is always very concerned about patient safety issues including the prevention of cross infection among patients through endoscopy.

As a result of our complaint investigations, Olympus has determined to revise our reprocessing instructions and recommends the use of an additional cleaning brush. The additional brush is the MAJ 1888. Olympus recommends brushing around the forceps elevator with the MAJ-1888 brush in addition to the existing MH-507 brush in order to adequately clean around the forceps elevator more thoroughly. The reprocessing manual was updated accordingly.

For a detailed procedure, please refer to the enclosed updated reprocessing manual.

OLYMPUS regrets if the implementation of these measures might cause inconveniences and fully appreciates your prompt cooperation in addressing this situation. In case of any questions, please do not hesitate to contact your local vendor/OLYMPUS partner who will be delighted to support you or make the necessary arrangements.

Please fill out, sign and return the attached Reply Form to your local vendor/OLYMPUS partner.

Yours sincerely,

<Name>

<Position>

<Address>

<Contact information>

REPLY FORM

[Dept/Attn] Olympus France S.A.S
[Street No.]
[ZIP City]
Date
Ref No.
EXT-xxx
Technical Advice: Additional Cleaning Procedure of TJF-Q180V

Dear Sirs and Madams,

We herewith confirm the receipt of your customer letter. We will share this information with the relevant departments.

Name	
Hospital	
Department	
Street	
Postal Code/ City	

Appendix IV: Selected Adverse Event Reports

The following reports are copies of medical device reports and MedWatch reports sent by manufacturers and hospitals to FDA to account for incidents of antibiotic-resistant infections linked to ERCP procedures. This compilation is not inclusive of all device reports filed by manufacturers and hospitals but rather is meant to provide a sample of the reports for each outbreak of duodenoscope-linked infections between 2012 and spring 2015.

Advocate Good Samaritan Hospital Downers Grove, Illinois

Ł	S. Department of Health and Human Services	For use by us	er-facilities,	1	Report # 24312	93-2014-00	006
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CONFIDENTIAL

This section applies only to requirements of the Paperwork Reduction Act of 1995. This section applies only to requirements of the equivor (certain act of 1990). The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gethering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

FUJIFILM0000325

MDR 2431293-2014-00006

12/03/2014

(Continued from section H 10)

A letter was e-mailed to **explaining the Initial Reporter**, detailing inspection findings on the subject scopes, explaining the findings of general wear and tear. The letter further detailed FMSU-ESD's intent to replace the insertion sections assemblies and all internal channels on both subject endoscopes in an abundance of caution.

Repairs on both subject endoscopes were completed. The subject endoscopes passed QC inspection and were returned to the customer.

There has been no response to a Complaint Follow Up questionnaire sent to the customer requesting patient information about the incidents. In addition, the insertion section assemblies removed from the subject endoscopes were placed in quarantine, in case further examination is needed. No further similar complaints have been received from this customer or any other customer.

occurred.

confirmed there have been no further similar incidents since this reported incident further stated culturing of the endoscopes is performed monthly.

Page 3 of 3

Form Approved: OME No. 09 10-029 1, Expires 12/31/11 See OMB statement on reverse. Mfr Report #

2431293-2014-00002

UF/Importer Report #

U.S. Department of He	aith and	Human	Services
Food and Drug Adminis	tration		

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

MEDWATCH

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FORM FDA 3500	DA (1/09)		Page 1	of 2			FDA Use Only
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	of Event: or	Female	lbs	#1			
	Date		or	#2		• • • • • • • • • • • • • • • • • • • •	· · · · · · · · · · · · · · · · · · ·
In confidence	of Birth:	Male	kgs	2. Dose, Frequency & R	oute Used	3. Therapy I	Dates (If unknown, give duration)
B. ADVERSE EV	ENT OR PRODUCT	PROBLEM				from/to (or #1	best estimate)
1. 📝 Adverse Event	t and/or 🗌 Produ	ict Problem (e.g., defects/mall.	unctions)	#1			
2. Outcomes Attribute (Check all that apply		·		#2		#2	
Death:	77	Disability or Permanent Da	mage	4. Diagnosis for Use (In	dication}		Event Abated After Use Stopped or Dose Reduced?
Life-threatening	(mm/dd/yyyy)	Congenital Anomaly/Birth E	- [#1			Yes No Doesn't Apply
	+	Other Serious (Important M		#2			Doesn't
	· +	ent Impairment/Damage (Devic		6. Lot#	7. Exp. Date		
3. Date of Event (mm		Date of This Report (mm/do		#1			Event Reappeared After Reintroduction?
2	014	05/20/2014	1	#2	#2	#1	Yes No Doesn't Apply
5. Describe Event or		1	-	9. NDC# or Unique ID		#0	Doesn't
		al Systems U.S.A., ate Good Samaritan		10.0			С С Аррау
(AGSH)and advi	ised of Fujinon	(note: FMSU's endos	copes	10. Concomitant Medica	erroducts and Th	ierapy Dates (E)	xclude treatment of event)
		on") duodenoscopes CRE (carbapenem-re					
Enterobacteria	<i>b</i> 1	······································					
				D. SUSPECT MED	ICAL DEVICE		
				1. Brand Name Fujin			
				2. Common Device Nam	e Duodenosco		
				3. Manufacturer Name, 0			
				FUJIFILM Optical (Bitachicmiya City,	Corporation, 1		
				4. Model #	Lot#		5. Operator of Device
				ED-530XT		lan Bata (Health Professional
				Catalog #	Expirau	ion Date (mm/da	Lay User/Patient
				Serial #	Other #	ŧ	Other.
				ND102A125		1	
				6. If Implanted, Give Dat	te (mm/dd/yy)y)	7. If Explant	ed, Give Date (mm/dd/yyyy)
6. Relevant Tests/Lat	poratory Data, Including I	Dates		8. Is this a Single-use D	evice that was Re	processed and	Reused on a Patient?
				🗌 Yes 🔽 No			
				9. If Yes to Item No. 8, E	nter Name and Ac	dress of Repro	cessor
				10. Device Available for	Evaluation? (Do n	ot send to FDA)	······································
				🗌 Yes 🖌 No	Returned to	Manufacturer on	(mm/dd/yvyy)
				11. Concomitant Medica	Products and Th	erapy Dates (E	ixclude treatment of event)
7. Other Relevant His	tory, including Preexistin	ng Medical Conditions (e.g., a patic/renal dysfunction, etc.)	llergies.				
race, pregnancy, sm	noking and alconol use, he	patio/renal dysfunction, etc.)					
				E. INITIAL REPOR	TER		
				1. Name and Address	Phor	ne #	
							· · · · · · · · · · · · · · · · · · ·
				Advocate Good Sa			TT (0515
1				3815 Highland A	venue, Downe	rs Grove,	TP 60212
		titute an admission that ibutor, manufacturer or		2. Health Professional?			4. Initial Reporter Also Sent Report to FDA
caused or contribu	uted to the event.	and a manufacturer of	P100001	Yes 🗌 No	Administrator/Su	pervisor	Yes No Unk.

FDA USE ONLY MEDWATCH FORM FDA 3500A (1/09) (continued) Page 2 of 2 F. FOR USE BY USER FACILITY/IMPORTER (Devices Only) 1. Check One 2. UF/Importer Report Number User Facility Importer 3. User Facility or Importer Name/Address 4. Contact Person 5. Phone Number 6. Date User Facility or 7. Type of Report 8. Date of This Report (mm/dd/yyyy) Importer Became Aware of Event (mm/dd/yyyy) 🗍 Initial Follow-up # 9. Approximate Age of Device 10. Event Problem Codes (Refer to coding manual) Patient Code Device Code

Outpatient Diagnostic Facility

Ambulatory Surgical Facility

(Specify)

12. Location Where Event Occurred

Hospital

Nursing Home

Outpatient Treatment Facility

Home

Other:

G. ALL MANUFACTURERS	\$	
1. Contact Office - Name/Address (for Devices)		2. Phone Number
U.S.A, Inc. Endoscopy 10 High Point Drive, PUJIFILM Optical Corp Factory, 4112 Tono, H Ibaraki, Japan, 319-22	3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional	
A Date Received by Manufacturer (nsm/dd/yyyy) 05/20/2014 6. If IND, Give Protocol # (Check all that apoly) 5-day	5. (A)NDA # IND # STN # PMA/ 510(k) # E0 42075 Combination Product Yes Pre-1938 Yes OTC Product Yes 8. Adverse Event Term(s)	User Facility Company Representative Distributor Other:
The public reporting burden for this coll	ection of information has been	n estimated to average 66

11. Report Sent to FDA?

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

Yes _

No

🗌 Yes

🗌 No

The public reporting burden for this collection of information has been estimated to average 66 hinutes per rasponse, including the time for reviewing instructions, searching existing data burces, gathering and maintaining the data needed, and completing and reviewing the sollection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

H. UEVICE MANU		
1. Type of Reportable E	YOIL	2. If Follow-up, What Type?
Death		Correction
Serious Injury		Additional Information
Malfunction		Response to FDA Reque
	sitive Growth	Device Evaluation
3. Device Evaluated by 1		 Device Manufacture Date (mm/yyyy)
Vot Returned to I		04/25/2012
	ation Summary Attached	5. Labeled for Single Use?
provide code:	to explain why not) or	
		Yes V No
6. Evaluation Codes (Re	fer to coding manual)	
Method	3263 -	- , -
. .		
Results	3233 -	
Conclusions	11 -	
If Remedial Action Ini	liated, Check Type	8. Usage of Device
Recall	Notification	Initial Use of Device
Repair	Inspection	Reuse
Replace	Patient Monitoring	Unknown
Relabeling		9. If action reported to FDA under
	- Adjustment	21 USC 360i(f), list correction/ removal reporting number:
Other:		-
0. 📝 Additional Manu	acturer Narrative	and / or 11. Corrected Dat
UJIFILM Medical	Systems 0.S.A.	, Inc. (FMSU) immediate.
unitiated an inv	estigation, inc.	luding a visit to AGSH,
cronnel were i	nformed that. i	the incident. FMSU n response to CRE
ncidents at its	sister hospital	l, Advocate Lutheran
General, AGSH ha	d conducted a re	eview of prior medical
		re positive for CRE. At
		as been advised that two A045 and SN # ND102A125)
ave allegedly b	een cultured pos	sitive for CRE. Three
atients who had	undergone ERCP	procedures tested
Positive for CRE	and two of three	ee of these patients
customer is unsu	as consistent W: re whether the r	ith positive CRE. The patients transferred CRE
to the endoscope	or vice versa.	Non-FUJIFILM equipment,
ncluding a chan		vice instead of cleaning
ncluding a chan rush, is used t	o manually clear	vice instead of cleaning n the endoscopes and an
ncluding a chan Mush, is used t LER is used for	o manually clear automated high-1	vice instead of cleaning n the endoscopes and an level disinfection. A
ncluding a chan rush, is used t ER is used for eview of FMSU s	o manually clear automated high-1 ervice records f	vice instead of cleaning n the endoscopes and an level disinfection. A for AGSH indicated no
ncluding a chan rush, is used t ER is used for eview of FMSU s bnormalities ot ttributable to	o manually clear automated high-3 ervice records f her than general normal usage and	vice instead of cleaning the endoscopes and an level disinfection. A for AGSH indicated no l wear and tear repairs i handling of the device
ncluding a chan rush, is used t ER is used for eview of FMSU s bhormalities ot ttributable to MSU has request	o manually clear automated high-1 ervice records f her than general normal usage and ed but has not r	vice instead of cleaning a the endoscopes and an level disinfection. A for AGSH indicated no 1 wear and tear repairs i handling of the device received any informetion
ncluding a chan rush, is used t ER is used for eview of FMSU s bnormalities ot ttributable to MSU has request n any treatment	o manually clear automated high-1 ervice records f her than general normal usage and ed but has not r or hospitalizat	vice instead of cleaning in the endoscopes and an level disinfection. A for AGSH indicated no l wear and tear repairs i handling of the device received any information tions for these patients
ncluding a chan rush, is used t ER is used for eview of FMSU s bnormalities ot ttributable to MSU has request n any treatment t the time of t	o manually clear automated high-1 ervice records f her than general normal usage and ed but has not r or hospitalizat his initial repo	vice instead of cleaning in the endoscopes and an level disinfection. A for AGSH indicated no l wear and tear repairs i handling of the device received any information fions for these patients prt. In addition, FMSO
including a chan brush, is used to ER is used for review of FMSU s obnormalities of ettributable to TMSU has request on any treatment it the time of t has requested th positive for CRE	o manually clear automated high-1 ervice records f her than general normal usage and ed but has not r or hospitalizat his initial repo at the duodenosc be returned for	vice instead of cleaning in the endoscopes and an level disinfection. A for AGSH indicated no l wear and tear repairs i handling of the device received any information tions for these patients brt. In addition, FMSU copes that tested r a detailed examination
including a chan brush, is used to AER is used for review of FMSU s abnormalities of attributable to FMSU has request on any treatment at the time of t bas requested th positive for CRE To date, the cus	o manually clear automated high-1 ervice records f her than general hormal usage and ed but has not r or hospitalizat his initial repo at the duodenoso be returned for tomer has not re	vice instead of cleaning in the endoscopes and an level disinfection. A for AGSH indicated no l wear and tear repairs i handling of the device received any information tions for these patients but. In addition, FMSO copes that tested i a detailed examination sturned any duodenoscope
including a chan brush, is used to XER is used for review of FMSU s abnormalities of bitributable to MSU has request on any treatment at the time of t thas requested th bositive for CRE bo date, the cus to FMSU. The inv	o manually clear automated high-1 ervice records f her than general normal usage and ed but has not r or hospitalizat his initial repo at the duodenoso be returned for tomer has not re estigation is st	vice instead of cleaning a the endoscopes and an level disinfection. A for AGSH indicated no 1 wear and tear repairs i handling of the device received any information tions for these patients bort. In addition, FMSO copes that tested a detailed examination sturned any duodenoscope till ongoing. FMSD will
including a chan brush, is used to ER is used for review of FMSUs a bhormalities of bittributable to FMSU has request on any treatment at the time of t thas requested th boositive for CRE boositive for CRE to fMSU. The inv- submit a supplement	o manually clear automated high-1 ervice records f her than general normal usage and ed but has not r or hospitalizat his initial repo at the duodenoso be returned for tomer has not re estigation is st	vice instead of cleaning in the endoscopes and an level disinfection. A for AGSH indicated no l wear and tear repairs i handling of the device received any information tions for these patients but. In addition, FMSO copes that tested i a detailed examination sturned any duodenoscope
ncluding a chan rush, is used to ER is used for eview of FMSU s bhormalities ot ttributable to MSU has request n any treatment t the time of t as requested th ositive for CRE o date, the cus o FMSU. The inv	o manually clear automated high-1 ervice records f her than general normal usage and ed but has not r or hospitalizat his initial repo at the duodenoso be returned for tomer has not re estigation is st	vice instead of cleaning a the endoscopes and an level disinfection. A for AGSH indicated no 1 wear and tear repairs i handling of the device received any information tions for these patients bort. In addition, FMSO copes that tested a detailed examination sturned any duodenoscope till ongoing. FMSD will

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer (HFA-710) 5600 Fishers Lane Rockville, MD 20857 Please DO NOT RETURN this form to this address.

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Advocate Lutheran General Hospital Park Ridge, Illinois

U.S. Experiment of Health and Human Services importers, distributions, and analyzic futures (Interprete Security Control (Security 2012) (2000) Interprete Security (Security Control (Security Control (Security 2012) (2000) Interprete Security (Security Control (Security Contr	U.S. Department of Realth and Rul	i toi use by u	ser-facilities,		Approved. Onio	No. 10-029 1, Expires 12/31/11 See OMB statement on reverse.
MELDIVALUET POINT FLAT. UNCONTRACTION POINT		importers, distributor	· · · · · · · · · · · · · · · · · · ·	Mfr report #		
A PATIENT INFORMATION Source Control (Control (Contro(Control (Control (Control (Control (Control (Control (Control (Con	MEDWATCH	for MANDAT	ORY reporting	UF/Importer Report	#	
	FORM FDA 3500A (6/10)	Page	1 of <u>3</u>			FDA Use Only
	A. PATIENT INFORMATION		C. SUSPECT PROD	UCT(S)		
NA hoanitarios Charlesse Event OR PRODUCT PRODE M Charlesse Event College Antipole College Antipole </th <th>1. Patient Identifier 2. Age at Time</th> <th>3. Sex 4. Weight</th> <th></th> <th></th> <th></th> <th></th>	1. Patient Identifier 2. Age at Time	3. Sex 4. Weight				
b. confidence b			#1			
	N/A		#2			
			2. Dose, Frequency,& Route	Used		
1. So Advance family Product Preten (r.g., selects/instruction) 2. Concerning in the function of the select (response) 2. Concerning in the function of the select (response) 3. Due of the response (response) 3. Due of t			#1		#1	
2) "Outcome Attributed to Adverse Towns Description Disability or Parameter Damage Disability or Parameter D			#2		#2	
Decisity of Permanent Damage decisity of Permanent Damage decisity of Permanent Damage decisity of Permanent Damage (device) decisity of Permanent Damage (device) decisity permanent decisite decisite (decisity) decisity permanent decisite decisite (decisity) decisity permitting and incident tal. Advances decisity permitting and incident tal. Advances decisity decisity permitting and incident tal. Advances decisity permitting and decisits of from the customer confirmed tal. decisity decisity permitting and advances. Organism found under elevator on accepted decisity permitting and decisits permitting advances decisity permitting and decisits advances decisity permitting and decisits decisity permitting and decisits advances decisity permitting advances decisity	2. Outcomes Attributed to Adverse Event	LUCT Problem (e.g. derects/mairunctions)	4. Diagnosis for Use (Indicati	ion)		
(mediagly) (Life Treatment [] (Life Treatment		Disability or Permanent Damage	#1			- <u> </u>
Hoppstatzbor – Initial or prokingel Hop - Security (mythemet Parmaner Impairment Damage Genetar) A Date of The speet domaddyyyy (A Date of The speet domaddyyyy) A Date of The speet domaddyyyy (A Date of The speet domaddyyyy) A Date of The speet domaddyyyy (A Date of The speet domaddyyyy) A Date of The speet domaddyyyy (A Date of The speet domaddyyyy) A Date of The speet domaddyyyy (A Date of The speet domaddyyyy) A Date of The speet domaddyyyy (A Date of The speet domaddyyyy) A Date of The speet domaddyyyy (A Date of The speet domaddyyyy) A Date of The speet domaddyyyy (A Date of The speet domaddyyyy) A Date of The speet domaddyyyy (A Date of The speet domaddyyyy) A Date of The speet domaddyyyy (A Date of The speet domaddyyy) A Date of The speet domaddyyyy (A Date of The speet domaddyyy) A Date of The speet domaddyyyy (A Date of The speet domaddyyy) A Date of The speet domaddyyyy (A Date of The speet domaddyyy) A Date of The speet domaddyyyy (A Date of The speet domaddyyy) A Date of The speet domaddyyyy (A Date of The speet domaddyy) A Date of The speet domaddyyy (A Date of The speet domaddyy) A Date of The speet domaddyy (A Date of The speet domaddy) A Date of The speet domaddyy (A Date of The speet domaddy) A Date of The speet domaddy (A Date of The speet domaddy) A Date of The speet domaddy (A Date of The speet domaddy) A Date of The speet domaddy (A Date of The speet domaddy) A Date of The speet domaddy (A Date of The speet domaddy) A Date of The speet domaddy (A Date of The speet domaddy) A Date of The speet domaddy (A Date of The speet domadd) A Date of The speet domaddy (A Date of The speet domaddy (A Date Speet domaddy (A Date Speet domaddy (A Date of The			#2		^{#1} └_	
			#2		#2 [
3. Date of Event (considelyyyy) 4. Date of This report (considelyyyy) 41 41 41 42 11 11 11 11 11 11 11 12 11 11 11 12 11 11 12 11 11 12 11 11 12 11 11 12			6. Lot #	7. Exp Date	8. Even	t Reappeared After
Sound a lenning and the second and		,	#1	#1	Reintro	auction?
				π ι	— _{#1} _	
Cn August 29, 2013, PENTAX Medical received MedWatch Report (MWS0501036) regarding an incident at Advacate Lutheran General Hospital for the following: "Patient underwent an ERCP procedure sing a PENTAX ED-34901K, A110048 (see viewing duddenscope. Patient developed a CRE infection. Proper cleaning of scope confirmed as poet sing a PENTAX ED-34901K, A110048 (see viewing duddenscope. Patient information obtained from the customer confirmed there were a baland of a patients that branche infected with CRE after they underwore a CRDP view BENTAX (a110048). D. SUSPECT MEDICAL DEVICE 10. Concentrative Medical Monthage and Mathematic Medical Monthage a poet significant information. Distained from the customer confirmed there were a baland of a poet does not constitute an admission that medical 0. SUSPECT MEDICAL DEVICE 11. Concentrative Mathematical Medical Monthage PENTAX Medical, Monthage NJ 2. Common Divise Name Development Device Name Development Device Name PENTAX Medical Monthage, NJ 2. Concentrative Mathematical Medical Monthage PENTAX Medical Monthage, NJ 3. Relevant Testel Latoratory Date, Including Dates' No and magnetic medical Conditions (e.g., allerpies, mate, magnetic, conditing and allocal Conditions (e.g., allerpies, mate, magnetic, condaling and allocal Conditions (e.g., allerp	5. Describe Event or Problem			#2		
(MW:S031083) regarding an incident at Advocate Lutheran General Hospital for the following: "Patient uderwart at REPC proceedure using a PENTAX ED-3490TK A110044 side viewing duodenoscope." 10. Concombant Medical Products and therapy Dates (Enclude treatment of event) 10. Concombant Medical Products and therapy Dates (Enclude treatment of event) 10. Concombant Medical Products and therapy Dates (Enclude treatment of event) 10. Concombant Medical Products and therapy Dates (Enclude treatment of event) 10. Concombant Medical Products and therapy Dates (Enclude treatment of event) 10. Concombant Medical Products and therapy Dates (Enclude treatment of event) 10. Concombant Medical Products and therapy Dates (Enclude treatment of event) 10. Concombant Medical Products and therapy Dates (Enclude treatment of event) 10. Concombant Medical Products and therapy Dates (Enclude treatment of event) 10. Concombant Medical Monthale 10. Concombant Medical Monthale 10. Concombant Medical Monthale 10. Concombant Medical Monthale 10. Concombant Medical Monthale 10. Concombant Medical Monthale 10. Concombant Medical Monthale 10. Concombant Medical Monthale 10. Concombant Medical Monthale 10. Concombant Medical Monthale 10. Concombant Medical Monthale 10. Concombant Medical Monthale 10. Concombant Medical Monthale 10. Concombant Medical Monthale 10. Concombant Medical Monthale 10. Concombant Medical Monthale 10. Concombant Medica	On August 29, 2013, PENTAX Med	lical received MedWatch Report	9. NDC# or Unique ID		#2 L	Yes 🛄 No 📋 Apply
Using a PENTAX ED-3490TK A110084 side viewing ducidenoscope. Patient devices of CRE infection. Proprietioning discope confirmed Additional information obtained from the customer confirmed there were a total of 4 patients that become infected with CRE after they underwere ERCP using ED-3490TK, A110084: D.SUSPECT MEDICAL DEVICE 1. Brain Name PENTAX Common Device Name Common Device Name VIECD DUODENOSCOPE 3. Manufacture Name, City, MONVale, NJ 4. Mode # Description 6. Relevant Teste/ Laboratory Data, Including Dates' T/A 7. Other Relevant History, Including Pre existing Medical Conditions, etc.; N/A Via Submission of a report does not constitute an admission that medical products Submission of a report does not constitute an admission that medical Personnel, user facility, Importer, distibutor, manufacturer or product	(MW5031083) regarding an incider	t at Advocate Lutheran General	10. Concomitant Medical Pro	ducts and therapy Da	ates (Exclude trea	atment of event)
as per company recommendations. Organism found under elevator on scope." Additional information obtained from the customer confirmed there were a total of A patients that became infected with CRE after they underwert ERCP using ED-3490TK, A110084:	using a PENTAX ED-3490TK A110	084 side viewing duodenoscope.				
Additional information obtained from the customer confirmed there were a fold of A patients that became infacted with CRE after they underwert ERCP using ED-3490TK, A110084: D.SUSPECT MEDICAL DEVICE 1. Brand Name PENTAX 2. Common Device Name VIDEO DUODENOSCOPE 3. Manufacturer Name, City and State PENTAX Medical, Montraie, NI 4. Model # Common Device Name VIDEO DUODENOSCOPE 3. Manufacturer Name, City and State PENTAX Medical, Montraie, NI 4. Model # Cotations # 6. Relevant Testal Laboratory Date, Including Dates' 11. Concornitant Medical Products and Therapy Dates 12. Other Relevant History, Including Dates 13. Other Relevant History, Including Pre existing Medical Conditions (<i>e.t., allergies, relevant Medical Products and Therapy Dates</i> (Exclude treatment of arront) 10. Device Available for Evaluation? 11. Concornitant Medical Products and Therapy Dates (Exclude treatment of arront) 12. Other Relevant History, Including Pre existing Medical Conditions (<i>e.t., allergies, relevant</i>) 13. Device Available for Evaluation? 14. Instan emportune Aller Products and Therapy Dates (Exclude treatment of arront) 15. Other Relevant History, Including Pre existing Medical Conditions (<i>e.t., allergies, relevant</i>) 16. If the there Note: Relevant Medica	as per company recommendations.					
a total of 4 patients that became infected with CRE after they underwork D.SUSPECT MEDICAL DEVICE ERCP using ED-3490TK, A110084: Iterand Name D.SUSPECT MEDICAL DEVICE Iterand Name Iterand Name D.SUSPECT MEDICAL DEVICE Iterand Natom D.SUS						
In the set of the s	a total of 4 patients that became inf	ected with CRE after they underwent	D. SUSPECT MEDIC	CAL DEVICE		
	ERCP using ED-3490TK, A110084	:				
			2. Common Device Name		55	
PENTAX Medical, Montvale, NJ 4. Model # Lot #					PE	
			PENTAX Medical,	Montvale, NJ		Γ
Catalog # Expiration Date (mm/dd/yyyy) A Health Professional G. Relevant Tests/ Laboratory Data, Including Dates' Other # Image: Catalog # Expiration Date (mm/dd/yyyy) 6. Relevant Tests/ Laboratory Data, Including Dates' Others Image: Catalog # Expiration Date (mm/dd/yyyy) 6. Relevant Tests/ Laboratory Data, Including Dates' Others Image: Catalog # Expiration Date (mm/dd/yyyy) 7. N/a 6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Image: Yes ID Item No. 8, Enter Name and Address of Reprocessor 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor 10. Device Available for Evaluation? (Do not send to FDA) (mm/dd/yyyy) Image: Yes ID Item No. 8, Enter Name and Address of Reprocessor (mm/dd/yyyy) 11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (mm/dd/yyyy) 11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (mm/dd/yyyy) 11. Name and Address Phone # Patient Information Image: Products and Therapy Dates (Exclude treatment of event) (mm/dd/yyyy) 11. Name and Address Phone # Patient Information Image: Productores				Lot #		5. Operator of Device
A110084 Image: Control of the contr						
A 110084 Other: 6. Relevant Tests/ Laboratory Data, Including Dates' 0. If Implanted, Give Data (mm/dd/yyyy) 7. If Explanted, Give Data (mm/dd/yyyy) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? 9. If Yes Is this a Single-use Device that was Reprocessed and Reused on a Patient? 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor 10. Device Available for Evaluation? (<i>Do not send to FDA</i>) 10. The Relevant History, Including Pre existing Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic dystunctions, etc.) 11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) see page 3 of 3, Concomitant Medical products 7. Other Relevant History, Including Pre existing Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic dystunctions, etc.) 11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) see page 3 of 3, Concomitant Medical products 11. Name and Address Phone # Prone # Prone # Prone # Patient Information 1775 Dempster SL, Park Ridge, IL 60068 2. Health Professional? 2. Health Professional? 3. Occupation 2. Health Professional? 3. Occupation				Expiration Date	e (mm/dd/yyyy)	Health Professional
6. Relevant Tests/ Laboratory Data, Including Dates' n/a 6. Relevant Tests/ Laboratory Data, Including Dates' n/a 6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?			Catalog #		e (mm/dd/yyyy)	_
n/a 6. If Implanted, Give Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy) 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?			Catalog # Serial #		e (mm/dd/yyyy)	Lay User/ Patient
Image: Second	6 Relayant Tarta/Laboratory Data Jacilydiag Dat		Catalog # Serial #		e (mm/dd/yyyy)	Lay User/ Patient
Image: Second		es'	Catalog # Serial # A110084	Other #		Lay User/ Patient
7. Other Relevant History, Including Pre existing Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/ dysfunctions, etc.) 10. Device Available for Evaluation? (Do not send to FDA) 7. Other Relevant History, Including Pre existing Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/ dysfunctions, etc.) 11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) 8 See page 3 of 3, Concomitant Medical products 11. Name and Address 9 Phone # Patient Information 17.75 Dempster St. Patient Information Activica E Lutheran General Hospital 1775 Dempster St. Park Ridge, IL 60068 2. Health Professional? 2. Health Professional? 3. Occupation 4. Initial reporter Also Sent Report to FDA		es'	Catalog # Serial # A110084 6. If Implanted, Give Date (m	Other #	7. If Explanted,	Lay User/ Patient Other: Give Date (mm/dd/yyyy)
Image: Submission of a report does not constitute an admission that medical personnel, user facility, Importer, distributor, manufacturer or product Image: Product and Products and Therapy Dates (Exclude treatment of event) Submission of a report does not constitute an admission that medical personnel, user facility, Importer, distributor, manufacturer or product Image: Product and Products and Therapy Dates (Exclude treatment of event) Submission of a report does not constitute an admission that medical personnel, user facility, Importer, distributor, manufacturer or product Image: Product and Prod		es'	Catalog # Serial # A110084 6. If Implanted, Give Date (m 8. Is this a Single-use Device	Other #	7. If Explanted,	Lay User/ Patient Other: Give Date (mm/dd/yyyy)
7. Other Relevant History, Including Pre existing Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/ dystunctions, etc.) 11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) 8. INITIAL REPORTER 1. Name and Address Phone # Patient Information 1. Name and Address Phone # Patient Information Patient Information Address Park Ridge, IL 60068 Address Park Ridge, IL 60068 Address		ies'	Catalog # Serial # A110084 6. If Implanted, Give Date (m 8. Is this a Single-use Device Yes X No	Other #	7. If Explanted, ed and Reused o	Lay User/ Patient Other: Give Date (mm/dd/yyyy)
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 7. Other Relevant History, Including Pre existing Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/dysfunctions, etc.) n/a E. INITIAL REPORTER Name and Address Phone # Patient Information Advocate Lutheran General Hospital T75 Dempster St. Park Ridge, IL 60068 Submission of a report does not constitute an admission that medical personnel, user facility, Importer, distributor, manufacturer or product Advocate Data No 		les'	Catalog # Serial # A110084 6. If Implanted, Give Date (m 8. Is this a Single-use Device Yes No 9. If Yes to Item No. 8, Enter 10. Device Available for Eva	Other # m/dd/yyyyy) that was Reprocess Name and Address of luation? (Do not send	7. If Explanted, ed and Reused o of Reprocessor	Lay User/ Patient Other: Give Date (mm/dd/yyyy) n a Patient?
n/a E. INITIAL REPORTER 1. Name and Address Phone # Patient Information Patient Information Advocate Lutheran General Hospital Advocate Lutheran General Hospital Advocate Lutheran General Hospital T75 Dempster St. Park Ridge, IL 60068 Submission of a report does not constitute an admission that medical personnel, user facility, Importer, distributor, manufacturer or product 3. Occupation At Yes No		ies'	Catalog # Serial # A110084 6. If Implanted, Give Date (m) 8. Is this a Single-use Device ☐ Yes ☑ No 9. If Yes to Item No. 8, Enter 10. Device Available for Eva ☐ Yes ☑ No	Other # m/dd/yyyyy) that was Reprocess Name and Address of luation? (Do not send) Returned to Mage	7. If Explanted, ed and Reused o of Reprocessor of to FDA) anufacturer on:	Lay User/ Patient Other: Give Date (mm/dd/yyyy) n a Patient? (mm/dd/yyyy)
ETINITIAL REPORTER 1. Name and Address Phone # Patient Information 1. Name and Address Phone # Patient Information Advocate Lutheran General Hospital 1775 Dempster St. Park Ridge, IL 60068 2. Health Professional? Bubmission of a report does not constitute an admission that medical personnel, user facility, Importer, distributor, manufacturer or product	n/a 7. Other Relevant History, Including Pre existing I	Medical Conditions (e.g., allergies,	Catalog # Serial # A110084 6. If Implanted, Give Date (m) 8. Is this a Single-use Device Yes No 9. If Yes to Item No. 8, Enter 10. Device Available for Eva Yes No 10. Device Available for Eva Yes No 11. Concomitant Medical Pro	Other # Other # m/dd/yyyy) that was Reprocesse Name and Address of Luation? (Do not send Returned to Ma ducts and Therapy D	7. If Explanted, (ed and Reused o of Reprocessor d to FDA) anufacturer on: ates (Exclude tre	Lay User/ Patient Other: Give Date (mm/dd/yyyy) n a Patient? (mm/dd/yyyy)
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Submission of a report does not constitute an admission that medical personnel, user facility, Importer, distributor, manufacturer or product 4. Initial reporter Also Sent Report to FDA A Data Sent Report to	n/a 7. Other Relevant History, Including Pre existing I race, pregnancy, smoking and alcohol use, he	Medical Conditions (e.g., allergies,	Catalog # Serial # A110084 6. If Implanted, Give Date (m) 8. Is this a Single-use Device Yes Yes No 9. If Yes to Item No. 8, Enter 10. Device Available for Eva Yes Yes Yes No 11. Concomitant Medical Prosee page 3 of 3, Co E. INITIAL REPOR 1. Name and Address Patient Information	Other # m/dd/yyyyy) that was Reprocesson Name and Address of Name an	7. If Explanted, (ed and Reused o of Reprocessor d to FDA) anufacturer on: ates (Exclude tree cal products	Lay User/ Patient Other: Give Date (mm/dd/yyyy) n a Patient? (mm/dd/yyyy) vatment of event)
personnel, user facility, Importer, distributor, manufacturer or product	n/a 7. Other Relevant History, Including Pre existing I race, pregnancy, smoking and alcohol use, he	Medical Conditions (e.g., allergies,	Catalog # Serial # A110084 6. If Implanted, Give Date (m) 8. Is this a Single-use Device ☐ Yes ☑ No 9. If Yes to Item No. 8, Enter 10. Device Available for Eva ☐ Yes ☑ No 11. Concomitant Medical Pro See page 3 of 3, Co E. INITIAL REPOR 1. Name and Address Patient Information Addvocate Lutheran Ge 1775 Dempster St.	Other # m/dd/yyyyy) that was Reprocesson Name and Address of Name an	7. If Explanted, (ed and Reused o of Reprocessor d to FDA) anufacturer on: ates (Exclude tree cal products	Lay User/ Patient Other: Give Date (mm/dd/yyyy) n a Patient? (mm/dd/yyyy) vatment of event)
personnel, user facility, Importer, distributor, manufacturer or product	n/a 7. Other Relevant History, Including Pre existing I race, pregnancy, smoking and alcohol use, he	Medical Conditions (e.g., allergies,	Catalog # Serial # A110084 6. If Implanted, Give Date (m) 8. Is this a Single-use Device ☐ Yes ☑ No 9. If Yes to Item No. 8, Enter 10. Device Available for Eva ☐ Yes ☑ No 11. Concomitant Medical Pro See page 3 of 3, Co E. INITIAL REPOR 1. Name and Address Patient Information Addvocate Lutheran Ge 1775 Dempster St.	Other # m/dd/yyyyy) that was Reprocesson Name and Address of Name an	7. If Explanted, (ed and Reused o of Reprocessor d to FDA) anufacturer on: ates (Exclude tree cal products	Lay User/ Patient Other: Give Date (mm/dd/yyyy) n a Patient? (mm/dd/yyyy) vatment of event)
	n/a 7. Other Relevant History, Including Pre existing I race, pregnancy, smoking and alcohol use, hey n/a	Medical Conditions (e.g., allergies, batic/ dysfunctions, etc.)	Catalog # Serial # A110084 6. If Implanted, Give Date (m 8. Is this a Single-use Device ☐ Yes ☑ No 9. If Yes to Item No. 8, Enter 10. Device Available for Eva ☐ Yes ☑ No 11. Concomitant Medical Pro see page 3 of 3, Co E. INITIAL REPOR 1. Name and Address Patient Information Addvocate Lutheran Ge 1775 Dempster St. Park Ridge, IL 60068	Other # m/dd/yyyyy) that was Reprocesse Name and Address of luation? (Do not send Control Control Control Returned to Ma ducts and Therapy D ncomitant Media TER eneral Hospital	7. If Explanted, (ed and Reused o of Reprocessor d to FDA) anufacturer on: ates (Exclude tree cal products	Lay User/ Patient Other: Give Date (mm/dd/yyyy) n a Patient? (mm/dd/yyyy) eatment of event) ent information

FORM FDA 3500A (6/10))	Page 2	of <u>3</u>		
	2. UF/ Import nporter 2518897-2	(<i>DEVICES Only)</i> er Report Number 2013-00004	1. Type of Reportabl		2. If Follow-up, What Type?
 User facility or Importer Name/ Pentax Medical Paragon Drive Montvale, NJ 07645 	Address		Serious Injury Malfunction Other 3. Device Evaluated		Additional Information Additional Information Response to FDA Request Device Evaluation 4. Device Manufacture Date
4. Contact Person	7. Type of Report	Phone Number	Not Returned	-	(mm/dd/yyyy) 04/02/2009
6. Date User facility or Importer Became Aware of Event (mm/dd/yyyy) 08/29/2013	Initial	8. Date of This Report (mm/dd/yyyy) 09/20/2013	See H.10 belo		5. Labeled for Single Use?
9. Approximate Age of Device 10. Event P Patient Code 2 Device Code 11. Report Send to FDA?	1735 - 1091 - 23 12. Location Where Event O - -	 03	6. Evaluation Codes Method Results Conclusions	(Refer to coding manual) 10 - 204 - 234 46 - 54	
Yes 09/20/2013 No (mm/dd/yyyy) 13. Report Sent to Manufacturer? Yes 09/20/2013 No (mm/dd/yyyy)	Outpatient Treatment Facility Other:	Outpatient Diagnostic Facility Ambulatory Surgical Center (Specify)	Recall Repair Replace Relabeling	a Initiated, Check Type b Initiated, Check Type b Notification b Inspection b Patient Monitoring b Modification/ Adjustment b H.10 below b Model Check Check Content b Model Check	8. Usage of Device Initial Use of Device Reuse Unknown If action reported to FDA under 21 USC 360 I(f), list correction/ removal reporting number:
 Manufacturers Name and Add Hoya Corporation PEN 30-2 Okada Aza-Shimo Tuskidate, Kurihara-shi G. ALL MANUFACTUR Contact Office – Name/ Address for devices) 	TAX Miyagi Factory omiyano i, Miyagi, Japan 987-22 ERS	203	During a cont Sept. 6, 2013 carbapenem- undergoing E These patien patients scree	, PENTAX was inform resistant Enterobacte RCP procedures usin ts were treated with a ened positive for CRE	and/or 11. Corrected Data cate Lutheran General Hospital on hed that four patients developed riaceae (CRE) infection after og scope ED-3490TK, A110084. ntibiotics. Twenty-two additional but did not develop an infection, this s used on the patients for ERCP.
Contact Office = see F. Manufacturing Site = se		3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional	The scope wa behind the el- confirmed tha their scopes. Pull-Thru The enzymatic de OPA is used	as tested at the user freevator and through the tot non-PENTAX brush The cleaning brushes Pre-Cleaning Device. tergent/cleaner used to for High Level Disinfe	acility and positive culture was found e hole of the scope. Customer es are used to manually reprocess s used at the facility are Medivators In addition, Surg-Enz® is the to reprocess the scope and Cidex ction.
4. Date Received by Manufacture 08/29/2013	r 5. (A)NDA #	User facility	Use (IFU), it s recessed are cleaned with C9S) and	specifically states that as around the elevato	essing/Maintenance Instruction For user must "Be aware that all r mechanism should be thoroughly d cylinder cleaning brush (e.g. CS-
6. If IND, Give Protocol # 7. Type of Report (Check all that apply) 5. 50 cm. M 20 dow	IND # IND # STN # PMA/ 510K # K092710 Combination Yes	Distributor Other: MEDWATCH	considered of Reprocessing ONLY PENT should be use Surg-Enz is r	ff-label use. Accordin g/Mainentance IFU, Pl AX cleaning brushes s ed to manually clean f	ENTAX highly recommends that specified in our instructions for use PENTAX endoscopes. In addition, 'AX Medical approved list of
5-day X 30-day 7-day Periodic 10-day Initial 15-day Follow-up#	Pre-1938 Yes OTC Product Yes 8. Adverse Event Term(s)		being held by	the Center of Diseas not been able to eval	ten out of commision and is currently e Control (CDC). Therefore, luate the scope.
2518897-2013-00004	n/a				

The public reporting burden for this collection of information has been established to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850 *Please DO NOT RETURN this form to this address*

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

B.5. Describe Event or Problem (continued)

B.6. Relevant Test/ Laboratory Data, Including Dates (continued)

Concomitant Medical Products and Therapy Dates (exclude treatment of event) (For continuation of C.10 and/ or D.11; please distinguish)

F10 Device Code 1091 =Device Cleaning Issue; 2303 = Bacterial contamination of device H.6 Evaluation Codes _Method 10 = Actual device involved in incident was evaluated _Results 204 = Disinfection error; 234 = Reuse of device without following disinfection/sterilization instructions _Conclusion 46 = Device failure indirectly contributed to event, 54 = Device was out of specification in a manner that relates to event	С	Other Remarks F10 Patient Code	1735 = Infection, Bacterial
H.6 Evaluation Codes _Method 10 = Actual device involved in incident was evaluated _Results 204 = Disinfection error; 234 = Reuse of device without following disinfection/sterilization instructions		F10 Device Code	1091 =Device Cleaning Issue;
_Method10 = Actual device involved in incident was evaluated_Results204 = Disinfection error; 234 = Reuse of device without following disinfection/sterilization instructions			2303 = Bacterial contamination of device
234 = Reuse of device without following disinfection/sterilization instructions			
_Conclusion 46 = Device failure indirectly contributed to event, 54 = Device was out of specification in a manner that relates to event		_Results	
		_Conclusion	46 = Device failure indirectly contributed to event, 54 = Device was out of specification in a manner that relates to event

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc) (continued)

Page 3 of 3

FORM FDA 3500A (6/10)

U.S. Department of Health and Human Services	s
Food and Drug Administration	

FORM FDA 3500A (2/13)

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

UF/Importer Report #	0.5.4		0.04	
	251	8897-	-201	3 - 00004

Mfr Report #

FORM FDA 3500A (2/13)	Pa	age 1 of <u>3</u>				FDA Use Only
A. PATIENT INFORMATION		C. SUS	PECT PRODU	CT(S)		
1. Patient Identifier 2. Age at Time of Event:	3. Sex 4. Weig	ght 1. Name	Give labeled streng	th & mfr/labeler)		
or	Female	_ lbs				
In confidence of Birth:	Male or	kas #2			-	
B. ADVERSE EVENT OR PRO		2. Dose,	Frequency & Route	Used	3. Therapy Dates (from/to (or best e	If unknown, give duration) stimate)
Adverse Event and/or	Product Problem (e.g., defects/malfunctions)	;) #1			#1	
Outcomes Attributed to Adverse Eve		#2			#2	
(Check all that apply)		4. Diagno	osis for Use (Indicat	ion)		Abated After Use ed or Dose Reduced?
Death:(mm/dd/yyyy)	Disability or Permanent Damage	#1				es 🗌 No 🗍 Doesn't
Life-threatening	Congenital Anomaly/Birth Defect	wents) #2				
Hospitalization - initial or prolonge Required Intervention to Prevent	Permanent Impairment/Damage (Devices)	6. Lot #	7	Exp. Date	#2 🗌 Y	
Date of Event (mm/dd/yyyy)	4. Date of This Report (mm/dd/yyyy)	#1	#	¥1		Reappeared After oduction?
	07/03/2014	#2	#	# 2	#1 🗌 Y	es No Doesn't Apply
Describe Event or Problem		9. NDC#	or Unique ID		#2 U V	Doesn't
er PENTAX Medical's inve?	estigation results, the CRE					
cases were limited to one	e hospital in Illinois and	10. Conc	omitant Medical Pro	oucts and The	rapy Dates (Exclude	treatment of event)
	eceived any other reports ED-3490TK to CRE infection si	nce				
he device received marke	et clearance in 2009. Post					
	for PENTAX Medical endoscope oducts have an excellent safe				(C	ontinue on page 3)
	ew of hospital procedures	D. SUS				
-	al was not using validated	1. Brand	Name			
	disinfectant products, nor w ent recommended by PENTAX		on Device Name		2b. P	rocode
edical for reprocessing	-	3 Manuf	acturer Name, City	and State		
	ated reprocessing protocol		acturer nume, ony	und otate		
example, while PENTAX Med	dical recommends the use of a			1		
	ning brush, investigation sho a non-bristled (squeegee-typ		#	Lot #		5. Operator of Device
channel cleaning device d	during the time leading up to		g #	Expiration	Date (mm/dd/yyyy)	Health Professional
the CRE incidents.		Serial			entifier (UDI) #	
		Senar	*	Onque la	entiner (ODI)#	
	(Continue on page	6. If Impl	anted, Give Date (m	m/dd/yyyy)	7. If Explanted, Giv	e Date (mm/dd/yyyy)
Relevant Tests/Laboratory Data, Incl			a Single-use Devic	e that was Ren	rocessed and Reuse	d on a Patient?
			-		rocessed and recuse	a on a r adent.
		9. If Yes	o Item No. 8, Enter	Name and Add	Iress of Reprocesso	-
		10. Devi c	e Available for Eva	luation? (Do no	t send to FDA)	
		Ye	s 🗌 No 🗌	Returned to N	lanufacturer on:	(mm/dd/yyyy)
	(Continue on page	3) 11. Conc	omitant Medical Pro	oducts and The	rapy Dates (Exclude	
	reexisting Medical Conditions (e.g., allergies,	~				
race, pregnancy, smoking and alcohol	use, nepatic/renal dystUnction, etc.)				(C	ontinue on page 3)
		E. INIT	IAL REPORTE	R	(0	
			and Address			
		Phone #		Ema	ail Address	
	(Continue on page	<u> </u>				
	t constitute an admission that medic r, distributor, manufacturer or produ		Professional? 3.	Occupation		nitial Reporter Also Sent Report to FDA
aused or contributed to the eve	ent.		s 🗌 No			Yes No Unk.

Page 2 of 3

FDA USE ONLY

FORM FDA 3500A	(2/13) (continu	ued)	Page 2	of <u>3</u>			
F. FOR USE BY U	SER FACILITY	IMPORTER (D	evices Only)	H. DEVICE MANUE	ACTURERS ONLY		
1. Check One		2. UF/Importer R	eport Number	1. Type of Reportable Eve	ent	2. If Follow-up, What Type?	
User Facility	Importer	2518897-201	3-00004	Death		Correction	
3. User Facility or Impor	rter Name/Address	•		Serious Injury		Additional Information	
				Malfunction		Response to FDA Request	
						Device Evaluation	
				3. Device Evaluated by M	anufacturer?	4. Device Manufacture Date	
				Not Returned to Ma		(mm/yyyy)	
4. Contact Person		5. Phone N	umber		tion Summary Attached		
					explain why not) or	5. Labeled for Single Use?	
6. Date User Facility or	7. Type o	of Report	8. Date of This Report	provide code:			
Importer Became Aware of Event (mm/c	<i>id/yyyy)</i> Initia		(mm/dd/yyyy)			Yes No	
· ·				6. Event Problem and Eva	luation Codes (Refer to a	oding manual)	
0. A		w-up #		Patient			
Age of Device		Codes (Refer to codir	ig manual)	Code [
	Patient Code	-	-	Device Code	-	-	
	Device			ſ			
	Code			Method			
11. Report Sent to FDA?		ation Where Event (Results	_]-[]	
Yes 7/03/2		Hospital	Outpatient Diagnostic Facility				
(<i>mm/dd/y</i>		Home	Ambulatory	Conclusions			
13. Report Sent to Manu	ifacturer?	Nursing Home	Surgical Facility	7. If Remedial Action Initia	ated, Check Type 8.	Usage of Device	
✓ Yes		Outpatient Treatmen Facility	t	Recall	Notification	Initial Use of Device	
(<i>mm/dd/y</i>	^(YYY)	Other:	(0) (1)		Inspection	Reuse	
14. Manufacturer Name/	Addross		(Specify)	Replace	Patient Monitoring	Unknown	
	Address			Relabeling	woulloadon	If action reported to FDA under 21 USC 360i(f), list correction/	
				Other	Adjustment	removal reporting number:	
				Other:			
				10. 🗌 Additional Manufa	acturer Narrative an	nd / or 11. 🖌 Corrected Data	
G. ALL MANUFAC							
1. Contact Office (and M	Ianufacturing Site	for Devices)	2. Phone Number	B.4, F.11, F.13 A	Added date;		
Name			0. Demost Oceano	B.5 Additional in	nformation added		
Address			 Report Source (Check all that apply) 				
			Foreign	F.2 Added UFI/Imp	porter Report Num	nber;	
			Study	F.7, G.7 Checked	Follow up #4;		
			Literature				
Email Address			Consumer	G.9 Removed Manu:	tacturer Report N	lumber;	
			Health Professional	H.2 Checked Correction and Additional Information;			
4. Date Received by	5.		User Facility				
Manufacturer (mm/dd)	⁽ yyyy) (A)ND	A #	Company Representative	H.10 Checked Corr	rected Data.		
		D#	Distributor				
6. If IND, Give Protocol #	# BL/	A #	Other:				
	PMA						
7. Type of Report	510(1						
(Check all that apply)		ination ct					
7-day Periodi							
10-day Initial	Pre-19						
15-day 🖌 Follow-	-up # _4 0101	Product Ves					
9. Manufacturer Report	Number 8. Adv	erse Event Term(s)					
This section applies		te of the Bananuar	Reduction Act of 1995.	Department of Health and H	uman Services	OMB Statement: "An agency may not	
The public reporting burde	n for this collection of	of information has bee	en estimated to average 66	Food and Drug Administration	on	conduct or sponsor, and a person is not	
minutes per response, incl sources, gathering and ma			searching existing data g and reviewing the collection	Office of Chief Information C Paperwork Reduction Act (P		required to respond to, a collection of information unless it displays a currently	
			y other aspect of this	PRAStaff@fda.hhs.gov		valid OMB control number."	

collection of information, including suggestions for reducing this burden to:

(CONTINUATION PAGE) For use by user-facilities, importers, distributors, and manufacturers for MANDATORY reporting

Page 3 of 3

B.5. Describe Event or Problem (continued)

FORM FDA 3500A (2/13) (continued)

MEDWATCH

B.5

Back to Item

Back to Item B.6

Back to Item B.7

Back to Item D.11 Back to Item C.10

PENTAX Medical retrained ALGH personnel on both reprocessing and pre-procedural performance check activities for the device on July 17, 2013. In addition, in October 2013, the hospital implemented its own initiative to sterilize its duodenoscopes using ethylene oxide. During our investigation, PENTAX Medical determined that between March and July there had been five specific ED-3490TK duodenoscopes used on patients who either had an active infection or been screened and tested positive for CRE. The serial numbers of those devices are: Al10084, Al10574 and Al10299, Al10086 and Al10471. All of these endoscopes were tested for CRE and only one, Al10084, was found to be positive for CRE. As noted, PENTAX Medical has not received any reports of incidents of CRE infection for model ED-3490TK or any other PENTAX endoscope from any other hospitals. Therefore, PENTAX Medical considers this MedWatch report closed.

B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)

Other Remarks

3-52 ~

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 8.26-2	ಜಿಜ	28.23	

FORM FDA 3500A (6/	,, · ,	Page .	201 2	
	FACILITY/IMPORTER (C		H. DEVICE MANUFACTURERS ONLY	
1. Check One User Facility	2. UF/Importer F Importer 2518897~28		1. Type of Reportable Event	2. If Follow-up, What Type?
3. User Facility or Importar N		13-00002	Death	Correction
FENTAX of America,			Serieus Injury Mattuoction	Additional Information
3 Paragon Drive			Clover:	Response to FDA Raquest
Montvale, NJ 07645				
			3. Device Evaluated by Manufacturer?	 Device Manufacture Date (mm/y/yy)
4. Contact Person	5. Phone N	5 92151 cer	Ves Evaluation Summary Attached	08/01/2013
			No (Attach page to explain why not) or	5. Labeled for Single Use?
 Date User Facility or Importer Became Awars of Event (mm/dd/yyy 	7. Type of Report 9)	8. Date of This Report (mm/dd/yyy)	provide cade:	🗌 Yes 📝 No
09/30/2013	Follow-up #	10/28/2013	6. Evaluation Codes (Relar to cooling manual)	
	snt Problem Cudes (Refer to codi	i na manuali	Method 3263]
Age of Device Patien		1 [[] []	
3 months Code	" <u>1735</u> –		Results 3218	~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~
Device Code	^{9:} 1.091 ~ 230	3 ~	Conclusions 1.6 - 2.4] m [
11. Report Sent to FDA?	12. Location Whara Event	Occuried	7. If Remedial Action Initiated, Check Type 8.	Usage of Device
1		Cadpatient	Racell Notification	Initial Use of Device
Ves 10/28/2013 (mm/dd/yyyy)	Home	Diagnostic Facility	Repair Inspection	🖉 Reuse
13. Report Sent to Manufactu		Surgical Facility	Replace Patient Monitoring	Unknown
Ves 10/28/2013	Cutpsliant Treatmen Facility	nĝ		If action reported to FDA under 21 USC 359(f), list correction/
No (mm/dd/yyyy)	Other.		Cither:	removal reporting number;
14. Manufacturer Name/Addr		(Specify)		
(c) Alt: MANUEAGIU 1. Contest Difics - Neme/Add for Devices) Contest office - Manufacturing Sit	iness (and Menufecturing Site see F3 above	2. Phone Number 3. Report Source (Check all that apply) Foreign Study Literature Consumer Censumer Health Professional	Advocaté Lutheran General Mospita PENTAX was informed that one pat: carbapemem-resistant Enterobacter after undergoing ERCP procedures Al10574. Additional twelve paties CRE; nine pätients screened negat screened positive for CRE but did infection. The scope was tested at the user culture was found behind the eler hole of the scopë. Customer conf. brushes are used to manually repi scopes. The cleaning brushes used Medivators. In addition, Surg-En- detergent/cleaner used to reprove	ient developed riaceae (CRE) infection using scope ED-349GTX, hts were screened for tive and 3 patients 4 not develop an CRE facility and positive vator and through the irmed that non-FENTAX cocess the PENTAX d at the facility are the is the enzymatic ess the Scopes and is
 Date Received by Manufacturer (mm/dd/yyyy) 	5.	User Facility	is used for High Level Disinfect.	
09/30/2013	(AJNUA P	Representative	PENTAX Reprocessing/Maintenance	
6. It IND, Give Protocol #	#ND #	Distributor	(IFD), it specifically states the that all recessed areas around the that all recessed areas around the theta area around the theta area.	
.:	STN#		should be thoroughly cleaned with	
7. Type of Report (Chock all that apply)	PMA/ 510(x) # K092710		cylinder cleaning brush (s.g. CS) detergent solution."	(95) and in a cleaning
	Combination	· · · · · · · · · · · · · · · · · · ·	H6: Endoscope was evaluated by us	
☐ 5-day 🗹 30-day ☐ 7-day	Produčt Yes		culture (CRE) was found behind e scope has not yet been evaluated	
7-day Periodic	Prē-1938 🗌 Yes		Investigation is still ongoing.	wy rautes.
15-day Follow-up #	OTC Product Yes			
9. Manufacturer Report Num	ber 8. Adverse Event Term(s)	nl		
13-60307				
minutes per response, including sources, gathering and maintair collection of information. Send o	this collection of information has be the time for reviewing instructions, sing the date needed, and completi comments regarcing this burden est fuiding suggestions for reducing this	searching existing data ng and reviewing the smale or any other aspect of	Food and Drug Administration Office of Chief Information Officer 1353 Piecard Drivé, Room 400	CMB Statement: "An agency may not conduct or seonser and a person is not required to respond to, a collection of information unless it displays a currently valid CMB control number."

Please DO NOT RETURN this form to this address.

U.S. Department of Health and Humar Food and Drug Administration	ror use by	user-facilities, ors and manufacturers	Mir Report # 2	518897-201	See OMB statement on reverse 3-00005
MEDWATCH	for MANDAT	ORY reporting	UF/Importer Re	port #	
FORM FDA 3500A (6/10)	Page ·	l of ²			
A PATIENT INFORMATION 1. Patient Identifier 1. confidence 2		Construction of the second sec	ength & mit/labelar)	3. Therspy Dat from/to (or be #1 #2	FDA Usè Only SS (If unknown, give duration) SS estimats)
(Check all that apply)	Disability or Permanant Damage	4. Diagnosis for Use (Int	fication)		ent Absted After Use opped or Dose Reduced?
Death: (mm930/yyy) Life-threatening	Congenital Anomaly/Birth Defect	#1		5	Yes (No (Doesn't Apply
Hospitalization - initial or prolonged	Ciher Serious (Important Medical Events)	#2			Yes (No (Coësn't Apply
Required intervention to Prevent Perman	ent Impainment/Damage (Devices)	6. Lot#	7, Exp. Date		ent Responsed After
{	I. Date of This Report (mm/dd/yyyy)	*1	#1	Re	introduction?
Patient Information	09/30/2013	9. NDC# cr Unique ID	#2	#1	Yes () No () Doesn't Apply
5. Describe Eventer Problem On September 30, 2013 user fa follows: Patient underwent an	~ ~ ~	19. NOC# Cr Unique ID		#2 [Yes (No) Doesn't
and developsd an Carbapenem-r Enterobacterioaceae (CRE) inf received antibiotics. No furt available at this point about found behind elevator on scop NOVI R R NOVI R NOVI R NOVI R R R R R R R R R R R R R R R R R R R	ection. The patient her information is the patient. CRE organism	B. SISISIZ Reconnection B. SISISIZ Reconnection Brand Name PENTA Common Device Name Montvale, NJ Model # E0-3490TX Catalog # Serial #: Al10574 S. If Implanted, Give Data	X * VIDEO DUDODE Dity and State Inc. Lot # Expiration Other #	n Date (mns/dd/y)	5. Operator of Davios yy) Fisalth Professional Usy User/Patient Other: Give Data (mm/od/yyyy)
6. Relevant Tests/Laboratory Data, including	Dates	8. is this a Single-use D Yes Z No B. If Yes to Nem No. 8, E			
		10. Device Aveilable for	Returned to Mi	anulaciurar cri:	(mm/dd/yyyy) ude treatment of event)
 Other Relevant History, Including Pressisti race, pregnancy, smoking and electrol use, he 	ng Medical Conditions (s.g., allergies, paticirenal dystunction, atc.)				
		E INITIAL REPOR			
		1. Name and Address Patient Information Advocate Luther: 1775 Dempster S Park Ridge, IL	an General Ho treet	Patient Inform	
Submission of a monor data and	836, 189, 200 julion linkton store and store 3	2 Martin Barton 1	12 0000000		12 Jacobal Browning Class &
Submission of a report does not cons personnel, user facility, importer, dist caused or contributed to the event.	nuce an admission that medical ributor, manufacturar or product	2. Health Professional?	3. Occupation Other Healthcare	Professional	4. Initial Reporter Also Sent Report to FDA 8 Yes No Unk.



	For use by use	ser-facilities.	For		No. 10-029 1, Expires 12/31/11 See OMB statement on reverse.		
U.S. Department of Health and Huma Food and Drug Administration	importers, distributor	ters, distributors, and manufacturers		Mfr report # 2518897-2013-00006			
MEDWATCH	for MANDAT	ORY reporting	UF/Importer Repor				
FORM FDA 3500A (6/10)	Page	1 of <u>3</u>			FDA Use Only		
A. PATIENT INFORMATION 1. Patient Identifier 2.		C. SUSPECT PRC 1. Name (Give labeled str #1 #2					
In confidence		2. Dose, Frequency,& Ro	ute Used	3. Therapy Date From/ to (or b	s (If unknown, give duration) best estimate)		
B. ADVERSE EVENT OR PRODUCT	PROBLEM	#1		#1			
1. Adverse Event and/or Product 2. Outcomes Attributed to Adverse Event	Problem (e.g. defects/malfunctions)	#2		#2			
(Check all that apply)		4. Diagnosis for Use (Indi	ication)		t Abated After Use ped or Dose Reduced?		
Death: [Disability or Permanent Damage	#1					
Life-Threatening	Congenital Anomaly/ Birth Defect	— — — — — — — — — — — — — — — — —		#1 🗖	Yes No Doesn't Apply		
Hospitalization – Initial or prolonged	Other Serious (Important Medical Events)	#2		#2 [7]	Doesn't Yes 🗌 No 🔲 Apply		
Required intervention to Prevent Permanent li	mpairment/ Damage (devices)	6. Lot#	7. Exp Date	8. Event	t Reappeared After		
3. Date of Event (mm/dd/yyyy) 4.	Date of This report (mm/dd/yyyy) 10/18/2013	#1	#1	Reintroc	duction?		
5. Describe Event or Problem	uted en event es felleurs. Detient			— #1 🗖	Doesn't Yes No Apply		
On October 18, 2013 user facility repo underwent an Endoscopic Retrograde	e Cholangiopancreatography	#2 9. NDC# or Unique ID	#2	#2 [7]	Doesn't Yes 🗌 No 🔲 Apply		
(ERCP) procedure (date unknown) an resistant Enterobacterioaceae (CRE)	infection. The patient received			^{#2}			
antibiotics and was released from the further information is available at this		10. Concomitant Medical	Products and therapy D	ates (Exclude trea	atment of event)		
		D. SUSPECT ME	DICAL DEVICE				
		1. Brand Name PENTAX					
		2. Common Device Name VIDEO DUDODE					
		3. Manufacturer Name, C PENTAX of Amer Montvale, NJ					
		4. Model #	Lot #		5. Operator of Device		
		ED-3490TK Catalog #	Expiration Dat	te (mm/dd/yyyy)	Health Professional		
				(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Lay User/ Patient		
6. Relevant Tests/ Laboratory Data, Including Dates'		Serial # A110299	Other #		Other:		
Escherichia coli (E-coli) New Delhi Me organism - Date unknown	etallo-beta-lactamase (NDM)	6. If Implanted, Give Date	(mm/dd/yyyy)	7. If Explanted, (Give Date (mm/dd/yyyy)		
		8. Is this a Single-use Dev Yes 🛛 No	vice that was Reprocess	sed and Reused or	n a Patient?		
		9. If Yes to Item No. 8, En	ter Name and Address	of Reprocessor			
		10. Device Available for I	Evaluation? (Do not sen				
		11. Concomitant Medical	Products and Thompy [Datas (Exclude tre	(mm/dd/yyyy)		
 Other Relevant History, Including Pre existing Med race, pregnancy, smoking and alcohol use, hepati 	lical Conditions (e.g., allergies, c/ dysfunctions, etc.)						
		E. INITIAL REPC	DRTER	<u> </u>			
		1. Name and Address		Phone #	Patient Information		
		Patient Information Advocate Lutheran 1775 Dempster Str Park Ridge, IL 6000	eet				
Submission of a report does not constitute		2. Health Professional?	3. Occupation	1	4. Initial reporter Also Sent		
personnel, user facility, Importer, distribute cause or contributed to the event.		Yes No	Other Healthcar	re	Report to FDA		
			Professional				

Page 2 of 3

FORM FDA 3500A (6/10)		-	
F. FOR USE BY USER FACILITY/ IMPORTE	R (DEVICES Only)	H. DEVICE MANUFACTURERS ONLY	
	orter Report Number	1. Type of Reportable Event	2. If Follow-up, What Type?
	7-2013-00006	Death	
3. User facility or Importer Name/ Address		Serious Injury	Additional Information
Pentax Medical		Malfunction	Response to FDA Request
3 Paragon Drive		Other	Device Evaluation
Montvale, NJ 07645		3. Device Evaluated by Manufacturer?	4. Device Manufacture Date
		· · ·	(mm/dd/yyyy)
4. Contact Person	5. Phone Number	Not Returned to Manufacturer	08/03/2011
		Yes Evaluation Summary Attached	00,00,2011
6. Date User facility or Importer Became 7. Type of Report	 Date of This Report (mm/dd/yyyy) 	No (Attach page to explain why not) or	5. Labeled for Single Use?
Aware of Event (mm/dd/yyyy) Initial		provide code;	
10/18/2013 🔲 Follow-up #	11/12/2013		
		6. Evaluation Codes (Refer to coding manual)	
9. Approximate Age of Device 10. Event Problem Codes (Refer to code	ing manual)	Method 3263 -	
Patient 1735 -	-	Method 3263 -	
2 yrs		Results 3218 -	
Device 1091 - 2	2303 -		
		Conclusions 18 - 24	- -
11. Report Send to FDA? 12. Location Where Event		7. If Remedial Action Initiated, Check Type 8.	Usage of Device
X Yes 11/12/2013 Hospital	Outpatient Diagnostic Facility		Initial Use of Device
No (mm/dd/yyyy) Home		Repair Inspection	Reuse
13. Report Sent to Manufacturer? Nursing Home	Ambulatory	Replace Patient Monitoring	Unknown
Ves 11/12/2013 Outpatient Treatme	nt Surgical Center	Relabeling Modification/ 9.	If action reported to FDA under
			21 USC 360 I(f), list correction/ removal reporting number:
□ No (mm/dd/yyyy) □ Other:			
14. Manufacturers Name and Address	(Specify)	10. Additional Manufacturer Narrative ar	nd/ or 11. Corrected Data
G. ALL MANUFACTURERS 1. Contact Office - Name/ Address (and Manufacturing Site for devices) Contact Office = see F.3 above Manufacturing Site = see F.14 above 4. Date Received by Manufacturer 10/18/2013 6. If IND, Give Protocol # PMA/ K092710	2. Phone Number 800-431-5880 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User facility Company Representative Distributor Other:	 B5: During a conference call with Adverse on October 18, 2013, PENTAX was in developed carbapenem-resistant Enter after undergoing ERCP procedures us In addition, one patient was screened CRE infection. The scope was tested at the user facility behind the elevator and through the her confirmed that non-PENTAX brushes the PENTAX scopes. The cleaning brushed vators. In addition, Surg-Enz® is used to reprocess the scopes and is nof detergents. Metricide OPA is used to According to the PENTAX Reprocessity Use (IFU), it specifically states that us recessed areas around the elevator mc cleaned with an appropriately sized cy CSC9S) and in a cleaning detergent set found behind elevator. The actual sco PENTAX. Investigation is still ongoing 	formed that one patient robacteriaceae (CRE) infection sing scope ED-3490TK, A110299, for CRE but did not develop an ity and positive culture was found ole of the scope. Customer are used to manually reprocess ushes used at the facility are the enzymatic detergent/cleaner tot on the PENTAX approved list for High Level Disinfection. ing/Maintenance Instruction For er must "Be aware that all lechanism should be thoroughly /linder cleaning brush (e.g. olution."
7. Type of Report (Check all that apply) Combination Product Yes 5-day 30-day Pre-1938 Yes 7-day Periodic OTC Product Yes 10-day Initial OTC Product Yes 9. Manufacturer Report Number 2518897-2013-00006 8. Adverse Event Term(s Sources, gathering and maintaining the data needed, and collection of information. Send comments regarding this ib this collection of information, including suggestions for red	n has been established to average 66 nuclions, searching existing data	Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850	OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

FORM FDA 3500A (6/10)

B.5. Describe Event or Problem (continued)

B.6. Relevant Test/ Laboratory Data, Including Dates (continued)

Concomitant Medical Products and Therapy Dates (exclude treatment of event) (For continuation of C.10 and/ or D.11; please distinguish)

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc) (continued)

Other Remarks

F10 Patient Code 1735 = Infection, Bacterial

F10 Device Code 1091 =Device Cleaning Issue; 2303 = Bacterial contamination of device

H.6 Evaluation Codes _Method 3263 = ACTUAL DEVICE NOT EVALUATED

_Results 3218 = MICROBIAL CONTAMINATION

18 = FAILURE TO FOLLOW INSTRUCTIONS ; 24 = OFF-LABEL, UNAPPROVED, OR CONTRAINDICATED USE _Conclusion

(CONTINUATION PAGE) For use by user-facilities, importers, distributors, and manufacturers for MANDATORY reporting

Page 3 of 3

Form Approved: OMB No. 0910-0291, Expires: 8/30/2016 Set: OMB/statement on reverse

U.S. Department of Health and Humi Food and Drug Administration	an Services For	use by user-	facilities, nd manufacture	M	Report # 2	518897~2	013-09	006	an on ingresse.
MedWatch	importers, d for Ma	listributors a ANDATOR	nd manufacture Y reporting						
SVRES/ WW SR S & SY FORM FDA 3500A (2/13)		Page 1 of	2						
A STANIEVER (STO)			·····		9391111111111			F.	DA Use Only
1. Patient Identifier 2.			Name (Give labeled						
			#1	an angan a					
			*2				•••••		
			Dose, Frequency &	Route Us	ed	3. Therapy	Dates (if i	unknown, giv	ve duration)
E ADVERSE VENNOR PRODU			#1			prom/ta (c #1	or best èsti	imats)	
\$	duct Problem (e.g., delects/mailuncti	S 1	#2			*:			
 Outcomes Attributed to Adverse Event (Check all that apply) 		1 L	. Diagnosis for Use ((Indication)			Event Al	bated After	Use
Death:	[]] Disability or Permanent Cemage	•	#1				Stopped	or Dose Re	oduced?
[] Life-threatening	Congenital Anomaly/Birth Defec	ct 🛛	#2				d [] Yes	s [_]No	Doesn't Apply
[2] Hospitalization - initial or prolonged	Other Serious (Important Medic	al Events) E	. Lot #	7 Fy	cp. Date		12 []] Yes	s [] No	Duesn't Apply
[] Required Intervention to Prevent Perm	anent Impairment/Damage (Devices)		*1	#1	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			sappeared /	
3. Date of Event (mm/bb/yyyy)	4. Date of This Report (mm/dd/yyy)	» []-					Reintrod	luction?	
5. Describe Event or Problem	02/25/2014		/2 . NDC# or Unique ID	#2					Doesn't Apply
			. Topon of antique to				(2 []] Yes	s []] No	C Doesn't Apply
			0. Concomitant Medi	ical Produc	ts and Ther				
							(Co)	ntinue on ,	page 3)
		2 3 00	Band Name		8) 53/7/1995				
		· · · · ·							
		2	. Common Device Ni	sme			2b. Pro	apose	
		3	. Manufacturer Nami	e, City and	State	••••••			
		4	. Nodel #		Lot #		15	Operator o	of Device
							أعجمين	🛄 Health I	Professionai
			Catalog #		Expiration I	oste (muvoc	*99999	[] Lay Use	er/Patient
			Serial #		Unique ider	itifier (UDI) i	#	[]] Other:	
	(Continue on pa	1ge 3)	. If Implanted, Give I	oste (mm/d	wyyyy	7. If Explar	ited, Give	Cate (mm/d	(d/yyyyy)
6. Relevant Tests/Laboratory Data, includin Specimen from patient, and c	~	8	Is this a Single-use	Device th	at was Repri	cessed and	i Roused	on a Patieni	t?
resistant enterobacteriaceae	(CRE) on Patient Information ? ?	Pest -	Yes No						
results: Patient positive te	きて GR Patient Information	: 3	. If Yes to item No. 8	, Enter Nar	ns and Addr	ess of Repr	ccessor		
		1	0. Davice Available f						
			[]] Yes []] No	[]] R	eturned to Mi	anutacturer o	n:	imm/dd/vyr	w)
	(Continue on pa	10e 3)	1. Concomitant Med						
7. Other Relevant History, Including Preexis	sting Medical Conditions (e.g., silero)	Second Second							
race, pregnancy, smuking and alcoholuse. Sputum, E-Coli metallo-beta-		cal [(C.o.	ntinue on	5979 31
Effusion			ENINITIAN REPO	DRUER					
		1 800	. Name and Address						
ridoren en el este el e									
ritioners.									
		l lõ	hone #		Ems	Address			
<u>[</u>	(Continue on pa	minimum gu							
Submission of a report does not cor personnel, user facility, importer, di	Istitute an admission that me	dical 2	. Health Professiona	17 3. Occ	upation		4. Ini Re	tial Reports	n Also Sent
caused or contributed to the event.	www.wewsposepspireces.weedaweedas.cos 605 605 6	*****	🗍 Yes 🛄 No						lo []] Unk.

FORM FDA 3500A	. (2/13) (c	continued)		Page	2 of	i i i i i i i i i i i i i i i i i i i		
NAN ROLLANDER SY AVE	SERIER.	IIIII AZIMINI	DATE: NO	32/533 62/192		<u>DIRA</u> MA	alleno).IN	
1. Check One				and Number	1. Type of Reportable		lannnuunnuu	2. If Follow-up, What Type?
[]]] User Facility	[]] Import	er			Death			(2) Correction
3. User Facility or Impor	ter Name/A	ddress		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Serious Injury			2 Additional Information
					Malfunction			Response to FDA Request
								Oevice Evaluation
							0	
					3. Device Evaluated I	•		 Device Manufacture Date (mm/yyyy)
			hunninnin		Not Returned			
4. Contact Person			5. Phone N	umber	Yes ()Ev			
			ļ		No (Altach pa provide code:	ige to explain w	hy nol) ar	5. Labeled for Single Use?
 Date User Facility or Importer Became 		Type of Repo	n	 Bate of This Report (mm/dd/yyyy) 				() Yes (] No
Aware of Event (mm/d	(0/YYYY)	Initial						
	1]] Follow-up #			6. Event Problem and		odes (Helor II	o soding manual)
	0. Event Pr	oblem Codes (Refer to code	ig manualj	Pate Code	1 1934) -	~
Age of Device	Patient (Devi			
	Code		•	~	Code	•		
,	Device	}.	~	-	Metho	sol		
	Code (+11 1 mmm1 mm	Burner Providence			{		and tanana tanana and t
11. Report Sent to FDA?		12. Location W		Cutpatient	Resul	te	-	
Yes(mm/dd/y)		Hospite	2)	Diagnostic Facility		}		
() MD		Home	e Line	Ambulatory	Conclusion	ns {		
13. Report Sent to Manu	facturer?	Nursing Outpat	g Home Jent Treatmer	¹³ Surgical Facility t	7. If Remedial Action	Initiated, Cher	ck Type	5. Usage of Device
Yes		Facility		**	Recati	Notificati	no	[]] Initial Use of Device
No (mm/dd/y)	2220	[]] Other:			Repair	Inspectio	n	[]] Reuse
4.4 . 88	<u>.</u>			(Specify)	Replace	Patient N		[] Unknown
14 Manufacturer Name/	MUU1858-				Relabeling	Modifical	tan/	9. If action reported to FDA under
						····· Adjustme	ent	21 USC 360i(f), list correction/ removal reporting number:
:					Other:			
					10. 📝 Additional M	enufacturer Na	rrative	and / or 11. Z Corrected Data
CONADAN/MANUEPAC	ionaaa				810 Additiona	l Narrativ	/@:	
1. Contact Office (and M	lanulacturir	ng Sits for Dev	ices)	2. Phone Number				nal information.
Name				1	K K -			representatives from CDC
			iiinniniininnii-	3. Report Source	<u>к.</u> к			entioned by the CDC ional patients who were
Address				(Check all that apply)				ure positives (i.s.,
				Foreign				s), other than the one
				Study	patient			ortsd in the initial
• • •				(iii) Literature	3500A (submit) considered as			. That patient was s had developed an
Email Address				Consumer				ther, information was
				Health Professional	provided to o	ne additio	mal pati	ent (
4. Date Received by	seven	5.	nennennen en	User Facility	K X			aveillance culture
Manufacturer (mm/dd		(A)NDA #		Company Representative				information provided on we hospital (Advocate
01/28/20:		IND #		Distributor	General Rospi		11-4 KY TO	a nashrrar (yayadan a
6. If IND, Give Protocol i	Ŕ	BLA#		Cither:	811 Corrected	Data:		
	,			CDC	A2: Patient a	ge was rep	ported in	error, instead of (
7. Type of Report	••••••	PMA/ 510(k) #						
(Check all that apply)		Combination						
5-day () 30-day		Product	Yes 🗌					
7-day Period	80	Pre-1938	Yes					
10-day () initial		OTC Product						
[]] 15-day 🛛 🔀 Follow				<u> </u>				
9. Manufacturer Report	Number	8. Adverse E	iant Term(s)					
2518897-2013-00	006							
*****		<u>.</u>				ind Marcon 29		
				k Reduction Act of 1995. en estimated to average 66	Deperiment of Health a Food and Drug Admini		4.063	 OMB Statement: "An agency may not conduct or sponsor, and a person is not
minutes per response, ind	luding the tin	ns for reviewing	i instructions,	searching existing date.	Office of Chief informat	tion Officer		required to respond to, a collection of
sources, gathering and ma of information. Sand comm				ig and reviewing the collection ny other aspect of this -	PRAStaff@ida.hhs.go			Information unless it displays a currently valid OMB control number."

PRASIaff@ida.blis.gov vs8d OMB control numt Plesse DO NOT RETURN this form to the above PRA Staff email address.

The public reporting burden for this collection of information has been estimated to average 36 minutes par response, including the time for reviewing instructions, searching existing date. sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this adjection of information, including suggestions for reducing this burden to:

FORM	FDA	3500A	(2/13)
Ø.W.23	<u>Man</u>	SINIZO:	MANUEL

.S. Department of Health and He ood and Drug Administration	uman Services	For use by	user-façilities,	Mir Rep	ont# 2518897	-2013-(0006
MedWatch		For use by importers, distribut for MANDA7	ors and manufactu FORY reporting	TETS UF/Impo	rter Report #		
ORM FDA 3500A (2/13)		Page ·	1 of 2				
22. MEMORINE ORMANICON				internet and the second			FDA Use Or
Patient Identifier 2. Age at Time	3. S	ex 4. Weight	1 Name (Give label	an a	ibeler)		
			*1	•	·		
			*2				
			2. Dose, Frequenc	. & Route Head	13 There	www.Datas (lf unknown, give duration
VADVERSES	ninga secolement				from/	to (or best e	istimale)
Adverse Event and/or	Product Problem (e.g., c	efects/melfunctions)	#1 				
Outcomes Attributed to Adverse Ever (Check all that apply)	nt		#2		#2		
	Disability or Per	maneot Damage	4. Diagnosis for Us	e (Indication)			Abated After Use ed or Dose Reduced?
Death: (mm/daryyyy) []] Life-threatening			#1				/es []] No []] Does Appl
Contentional and Content of the second se	Congenital Ano	maryidens Deretit Important Medical Events)	#2			{	
Required Intervention to Prevent P	(ma)		6. Lot#	7. Exp. D	ie]#2 [_] ¥	/es ∭ No
Date of Event (mm/dd/yyyy)	4. Date of This Rep		\$1	#1		8. Event Reintr	Reappeared After oduction?
······································	,	25/2014	#2	#2		1	(es []] No []] Does Apply
Describe Event or Problem	{		9. NDC\$ or Unique	ID		1	····· Apply
						#2 ∏ Y	fes []] No []] Does Apply
			10. Concomitant M	edical Products as	d Therspy Date	s (Exclude	treatment of event)
			1. Brand Name	Name		2b. F	Procode
			3. Manufacturer Ne	me. City and State	\$		
			4. Model #	Lot	¥	; ;;;:::::::::::::::::::::::::::::::::	5. Operator of Device
			Catalog #		ration Date (mn		Lay User/Patient
			Serial#	Unic	ue identifier (UI	31) #	Other:
			6. If Implanted, Giv	e Date /mm/dd/vvv	y) 7. 19 Exr	Panted, Gi	ve Date (mm/dd/yyyy)
Relevant Tests/Laboratory Data, Inch.		ontinue on page 3)				,	
Newvant resignationarity traid, mon	anny Laus		8. is this a Single-u	No	-		
			3. If Yes to Item No	. 8, Enter Name ar	d Address of R	sprocesso:	٤
			10. Davice Availabi				
			Yes []]	No [] Return	ed to Manufactur	er on:	(mm/dd/yyyy)
			11. Concomitant M				
Other Relevant History, Including Pra	existing Medical Conditi	ontinue on page 3) ons (e.g., allergies) ion, etc.)			n marapy ward	o (1.404900	, a particular of exactly
						(0	Continue on pege 3)
				PORTER		, and the second se	
			1. Name and Addre	169			
		ontinue on page 3)	Phone *		Emiali Address	,	
bmission of a report does not	constitute an admis	sion that medical	2. Health Professio	mai? 3 Occupati	on		Initial Reporter Also Se
rsonnel, user facility, importer, used or contributed to the even		cturer or product	Yes N	0			Report to FDA
			2				were been

MedWatch

FORM FDA 3500A	A (2/13)	(continued)			Page	20	f <u>2</u>						
10/12/12/19/20/20/20	SEC.	enters 2015.1:20	Danes V		67777			DIAV/INIA	MANUU	A STERIOR OF STREET, ST	<u>ITINX</u>		
1. Check One		2 0)F/Importer F	leport Nu	mber	1	1. Ty	pe of Rep	ortable Ev	/ent		2. If Follow-up, What Type	?
[]] User Pacility	oqent []]							Death				Correction	
3. User Pacility or Impo	inter Name	Address						Serious	injury			Additional Informat	ion
								Mattune	noite			Response to FDA F	Reques
												Device Evaluation	
							3. Di	evice Evalu	lated by N	Aanuischurer?		4. Device Manufacture Dat	16
								Not Rel	turned to N	Aanutscturør		(mm(yyyy)	
4. Contact Person			5. Phone N	umber				Yes	Evalua	ation Summary Atta	ched		
								No (Att	ach page	to explain why not)	Dr.	5. Labeled for Single Use?	ÿ
6. Date User Facility or Importer Became	T	7 Type of Repo	ri		of This Report (d/yyyy)		-	provide	aode:			Yes No	
Aware of Event (mm/	(daliyyyy)	()) (rdilial		indir.									
000000		Eollow-up #	1			i i i i i i i i i i i i i i i i i i i	6. Es	vant Proble	im and Ev	raluation Codes (A	iefer to co	ding manual)	
3. Approximate	10 Event \$	Problem Codes	*****	l ino manus	\$	-			Patient Code	1930	~	-	
Age of Device	Patient			······			-		Device			······································	
a)	Code		~		L		-		Code	[]	-)
	Device		-	-	<u></u>				Method			~ ~	1
11. Report Sent to FDA	Code [112 Lagation V	Lunn Curch	}	£	-				L		. L	4
	t	12. Location V			utpatient	i.			Results	~		-	
Yes(mm/dd/)	www.	C Home	.con		agnostic Facility			0					7
1		Nursin	a Home		mbulatory urgicsł Facility		L		iclusions	L		<u> </u>	3
13. Report Sent to Man	utacturer?		tient Treatme	nt	orgines racing		{7. if	Remedial /	Action Init	listed, Check Type	8.	Usage of Device	
(Yes(mm/dd/)		Facility	é					[]] Recali	[] Notification		[] Initial Use of Device	
[]No [IIIIIII		Other		(Speci	fvi	-		[]] Repair	2]] Inspection		[iii] Reuse	
14. Manufacturer Name	Address	. <u>.</u>	******			xx ([]] Replaci] Patient Monitorir		Unknown	
								[]] Relabe	ling []	Modification/ Adjustment		If action reported to FDA un 21 USC 360i(f), list correctio	saer Sal
								Other:				removal reporting number:	
						1							
								Additio		facturer Narrative	······································	dia di Managa	
GNADNMANUIPA		P3000000000000000000000000000000000000					19 ⁰ . I.	Muunio	nos signo	iacioisi namanya	201 : C	d/or 11. [_] Correcti	sa asis
1. Contect Office (and i	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	vices)	2 Pho	ne Number	Π.							
Name													
				3. Rep:	at Source	-							
Addrass				1	ck all that apply)		Į.						
				For									
				Shu	•								
				Lite			i.						
Email Address				·	nsumer allh Profassional								
				3	er Facility								
 Date Received by Manufacturer (mm/de 	d/yyyy)	5.		1	ar haosiy mpany								
		(A)NDA #		Rej	presentative								
6. If IND, Give Protocol	8	# ND #		1	tributor								
		BLA #		(?) Osh	:87.								
		PMAV		000		, II.							
7. Type of Report (Check all that spply)		510(k) #											
[[] 5-day []] 30-da	Y.	Combination Product	Tes Yes			~ [
7-day []] Period	dic	Pre-1938	[]] Yes			-							
10-day []] Initial		OTC Product											
	v-up #												
8. Manufacturer Report	t Number	8. Adverse E	vent Tarm(s										
2518897-2013-00	9696						1						
						iii	-						
This section applies	s only to re	quirements of t	he Paparwoi	k Reduct	ion Act of 1885.	. ತಿಯು				Hanso Services		OMB Statement: "An agency	
The public reporting burd minutes per response, in						3		and Drug / e of Chief in				conduct or sponsor, and a per required to respond to, a colle	

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PRAStaff@itda.hhs.gov velid OMB control nums Please DO NOT RETURN this form to the above PRA Staff amail address.

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gethering and maintening the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other especi of this -collection of information, including suggestions for reducing this burden to:

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conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently velid OMB control number."

U.S. Department of Health and Human S	Services For new hurs	user-facilities,	Mir Report #	518897~201	
Food and Drug Administration	importers, distribute	ors and manufacturers			400002
MedWatch	for MANDAT	ORY reporting	UF/Importer Re	port #	N
FORM FDA 3500A (2/13)	Page 1	of 2			FDÄ Use Gnly
A PATIENT INFORMATION		C SUSPECTION			, are use only
1. Patient Identifier 2.		1. Nama (Give labeled sin #1			
		#2			
B ADVERSE EVENT OR PRODUCT	PROBLEM	2. Dose, Frequency & Ro	ute Used	3. Therapy Dat from/to (or be	es (il unknown, give duration) Ist estimate)
	t Problem (e.g., defects/mailunctions)	\$1		#1	
2. Outcomes Attributed to Adverse Event		#2		#2	
(Check all that apply)		4. Disgnosis for Use (Ind	leation)		ent Absted After Use
Death:	Disability or Permanent Damage	\$1		,	opped or Dose Reduced?
Life-threatening	Congenital Anomaly/Birth Defect			#1 .	Yes No Doesn't Apply
	Other Serious (Important Medical Events)	#2 6. Lot #	7. 5 12:45		Yes No Doesn't
Required Intervention to Prevent Permaner	nt impsirment/Damage (Devices)		7. Exp. Dete		, ihbi)
3. Date of Event (mm/dd/yyyy) 4. 1	Date of This Report (mm/dd/yyyy)	#1	#1		ent Reappeared After Introduction?
	03/06/2014	#2	\$2.	[**i []	Yes No Doesn't
5. Describe Event of Problem		9. NDC# or Unique ID			· ****3
It was reported by facility on patient had underwent Endoscop	~ .			# 2 {	Yes No Apply
cholangiopancreatography (SRCP)	Drocedure on Patient Information	10. Concomitant Medical	Products and The	rapy Dates (Exc)	ude treatment of event)
meet Wirman and was tested for CRE. To	est results Patient Information	÷		X	
Patient Information revealed patient tested					
resistant Enterobacteriaceae (developed an active CRE infect:					
					(Continue on page 3)
/ pneumoniae carbapenemase (KPC),) (MBL): New Délhi MBL (NDM); and C MBT (VIN) Additional information	-	D. SUSPECT MED	(9/410.19)31//[913		
MBL (VIM). Additional informat: revealed one more patient	ion from the facility tested	1. Brand Name PENTA)	VIDEO DUODE	enoscope	
		2. Common Device Nami	8		b. Procode
positive for CRE, but had not of infection. These both cases are		2 10 10 10 10 10 10 10 10 10 10 10 10 10	10		FDT
a are surveillance culture posit: I further information provided by	1	3. Manufacturer Name, C PENTAX Nedical, Mo			
d of 2 reports.		4. Model#	Lot #		5. Operator of Davice
		ED-3490TK			Vealth Professional
		Catalog #	Expiration	Date (mm/dd/yy)	// Lay User/Patient
		Serial \$	tinious Ida	ntifior (UDI) #	Other:
4		A110471	Grados tas	unum (menta	·····
		6. if Implanted, Give Date	s:(mm/dd/yyyy)	7. If Explanted	, Give Date (mm/dd/yyyy)
6. Relevant Tests/Laboratory Data, Including Da	(Continue on page 3)				
Specimen from patient, and cult resistant enterobacteriaceae (tured for Carbapenem CRE) on Patient Information Test	8. Is this s Single-use Ds Yes 7 No 9. If Yes to Item No. 8, Es			
results: Patient positive test	ວກ Patient Information	5. N 195 G ngin mu, 8, 6	nër Naline and Mulé	i san in Kabudda	22C1
		10. Device Available for I		•	
		🗌 Yesa 🖉 No	Returned to M	lanuiscturar on:	(mm/dd/yyyy)
	(Continue on page 3)	11. Concomitant Médical	Products and Tha	tapy Dates (Exc	
7. Other Relevant History, including Pressisting	3 Medical Conditions (e.g., allergies,				
race, pregnancy, smoking and elcohol use, hep	stickenet dysfonction, etc.)				(Continue on anua 2)
					(Continue on page 3)
		1. Name and Address			
		Patient Information			·
		Advocate Luthers		ospital	
***		1775 Dempster St Park Ridge, IL 6			
		Lass neader in c			
		Phone #		di Address	
	(Continue on page 3)	atient Information		ent Information 6a	dvocatehealth.com
Submission of a report does not consti personnel, user facility, importer, distri	tute an admission that medical butor, manufacturer or product	2. Health Professional?		and the state	4. Initial Reporter Also Sent Report to FDA
caused or contributed to the event.	www.v.v	Ves No	Other Health	care Profess	Yes No 🖉 Unk.

2011 (2013) (2014) (2014) MEDWATCH Page 2 of ² FORM FDA 3500A (2/13) (continued) F. FOR USE BY USER FACILITY/IMPORTER (Devices Only) H. DEVICE MANUFACTURERS ONLY 1. Check One 2. UF/importer Report Number 1. Type of Reportable Event 2. If Follow-up, What Type? User Fechity 📿 imponer 2518897~2014~00002 Ceath Correction 3. User Facility or Importer Name/Address 🗌 Sericus Injury Additional Information PENTAX Medical Malfunction Response to FDA Request 3 Paragon Drive Oevice Evaluation Montvale, NJ 07645 3. Device Evaluated by Manufacturer? 4. Device Manufacture Date (mm/yyyy) Not Returned to Manufacturer 06/13/2012 4. Contact Person 5. Phone Number Yes Evaluation Summary Attached 5. Labeled for Single Use7 No (Attach page to explain why not) or provide code; 6. Date User Facility or 7. Type of Report Date of This Report Yes V No importer Becam (mm/dd/yyyy) 81 Aware of Event (mm/dd/yyyy) 🕢 India 03/06/2014 6. Event Problem and Evaluation Codes (Refer to coding manual) 02/14/2014 Follow-up \$ Patient 1930 9. Approximate 10. Event Problem Codes (Refer to coding manual) Code Age of Device Device: Patiens 2930 Code 2yrs Code Device Method 3263 3317 Code 11. Report Sent to FDA? 12. Location Where Event Occurred 3221 Results Outpatient Diagnostic Facility 03/05/2014 2 Hospital Ves. (mm/ad/www) [] Home 67 Conclusions No Ambulatory Surgical Facility Nursing Home 13. Report Sent to Manufacturer? 7. If Remedial Action Initiated, Check Type 8. Usage of Device Outpatient Traatment Ves_ Facility Initial Use of Device 🗌 Recail Notification (mm/dd/yyyy) - No Other: 🗸 Reuse C Repair Inspection (Specify) Unknown Replace Patient Monitoring 14. Manufacturar Nama/Address Modification/ If action reported to FDA under 21 USC 360(f), list correction/ removal reporting number: Hoya Corporation PENTAX Miyagi Factory Relabeling Adjustment 30-2 Okada Aza-Shimomiyano Citrer: Tuskidate, Kurihara-shi, Miyagi, Japan 987-2203 10. 📝 Additional Manufacturar Narrative : and / or 11. Corrected Data **G. ALL MANUFACTURERS** H10 Additional Narrative: B5: PENTAX Medical was only recently (02/14/2014) made 1. Contact Office (and Manufacturing Site for Devices) 2. Phone Number aware of patients with CRE organism after undergoing Name ERCP procedure with scope (serial number A110471). The Report Source . (Check all that apply) scope was a loaner scope provided by FENTAX Medical and Address 3 Paragon Drive was shipped to the facility on 05/26/2013, and returned Foreign Montvale, NJ 07645 to PENTAX Medical on 08/16/2013. The facility did not Study test the scope for CRE. Boya Corporation PENTAX Miyagi Factory H3, H6: A review of the Device History Records (DHR) Uterature 30-2 Okada Aza-Shimomiyano showed there were no reports of any non-conformance Consumer issues during the manufacturing in-process and final Emal Address Professional inspection. The device was manufactured according to 🖉 User Facility Date Received by Manufacturer (mm/dd/yyyy) specifications. PENTAX did not evaluate the scope at the time of return from facility, as there were no reports Π Company (A)NDA # Representativa coming from the facility of any adverse events or 02/14/2014 Distributor IND # malfunctions associated with the scope. The scope has 6. If IND, Give Protocol # Other: since then been in use at other user facilities and SLA# there have been no reports coming out from those PMA/ facilities of any CRE cases associated with this scope. \$10(k) # K092710 7. Type of Report (Check all list apply) Combination 🗌 5-day 🖌 30-day Yes Product 7-48y Periodic Pre-1938 Yes 🗌 10-day 🖌 8 Jinai OTC Product Yes 15-day Follow-up # 9. Manufacturiar Report Number 8. Adverse Event Termisi 2518897-2014-00002 Department of Health and Human Services This section applies only to requirements of the Paperwork Reduction Act of 1995. OMB Statement: "An agency may not Food and Drug Administration The public reporting burden for this collection of information has been astimated to average 65 conduct or sponsor, and a person is not Office of Chief Information Officer required to respond to, a collection of

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The public reporting burden for this collection of information has been astimated to service and the service of 1938. The public reporting burden for this collection of information has been astimated to service age 60 minutes per response. Including the time for reviewing instructions, searching existing data sources, gathering and mainteening the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

information unless it displays a currently valid OMB control number.*

Therapy Dates (If unknown, give duration) from/to (or bast estimate)

5. Event Abated After Use Stopped or Dose Reduced? #1 Yes Nc Doesn't Apply #2 Yes No Daesn't

#1 Yes No Doesn't Apply #2 Yes No Doesn't

(Continue on page 3)

5. Operator of Device Health Professional

Lay User/Patient Ciher:

(Continue on page 3)

4. Initial Reporter Also Sent Report to FDA Yes No Unk.

7. If Explanted, Give Date (mm/dd/yyyy)

FDA Use Only

UF/Importer Report #

U.S. Department of Health and Human Services:	For use by user-facilities,
Food and Drug Administration	importers, distributors and manu
MEDWATCH	for MANDATORY reporti

tors and manufacturers TORY reporting Page 1 of 2

FORM FDA 3500A (2/13)		Page 1	of	2					FDA U
A PATIENT INFORMATION						3			
1. Patient identifier 2.	r T.		- i	1. Name (Give labeled str	əngih & i	nisAabətər)			
				#1			~		
				#2					
			1	2. Dose, Frequency & Ro	oute Use	đ	3. Therap	y Dates (/ (or best et	f unknown, give di slimalei
	Product Problëm (e.g., <i>defectermällum</i>	atanii)		#1			#1	,	
2. Outcomes Attributed to Adverse Even				#2	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		#2		
(Check all that spply)			1	4. Diagnosis for Use (Inc	lication)		1		Abated After Use
Death: (mm/ad/yyyy)	Disability or Parmanent Dama	ige i		*1					ed or Dose Reduc
Lueenresiening	Congenital Anomaly/Birth Def			#2				، نسک ، " 	······································
Hospitalization - initial or prolonged	5	1	Ţ.	3. Lot #	7. Ex	o. Date		#2 🗌 Y	es No
3. Date of Event (mm/dd/yyyy)	annanent impairment/Damage (Devices			¥1	#1				Reappeared After oduction?
s sale as even (mixed yyy)	4. Date of This Report (mm/dd/y) 03/06/2014	(1)		#2.	#2				
5. Describe Event or Problem				9. NDC# or Unique ID	l				
It was reported by facility patient had underwent Endo								#2 🗍 Y	es No
cholangiopancreatography	(ERCP) procedure on Patient Infor	mation	ſ	10 Concomitant Medica	l Produc	ts and The	rapy Dates	(Excludo i	resiment of event)
[manufacture and was tested for CI									
resistant Enterobacteriace	ae (CRE), but had not								
developed an active CRE in								œ	ontinue on pag
pnæumoniae cærbapenemase (MBL): New Delhi MBL (NDM)	•	,		D. SUSPECT MED		javioja.			
MBL (VIM). This is 2 of 2	reports.	-1	ſ	1. Brand Name					
				2. Common Device Nam	Ø.			Zb. P	rocode
				3. Manufacturer Name, (The and	Cinin			
					any and	Jiano			
			Í	1. Model \$		Lois			5. Operator of D
				Catalog \$		Expiration	Date (mm/c	<i>ταί γγγγ</i>)	Health Profe
				Serial #		lesiana irin	ntifier (UDI		Cuther:
				201101 #		កលេវិកទ ខេត	uuus (ooi	3 8 :	
	(Continue on (1 ir ener	dilling	6. If Implanted, Give Dat	ន (៣៣/៨:	ÚYYYYY)	7. If Expla	inted, Giv	e Date (mm/dd/yy
6. Relevant Tests/Laboratory Date, Incl.	······	1090 0/		5. Is this a Single-use D	nidoo ina	6		nd Davina	d an a Distant
Specimen from patient, and resistant enterobacteriace			ľ	Yes No	ю ж (Сю-1) 18	1 Mar 2003	000000000000000000000000000000000000000	in trainside	u un a r attaint i
resistant enteropacteriace results: Patient positive		rest		9. If Yes to item No. 8, E	nter Nan	ie and Add	reas of Rep	XUC688907	·
	L								
			-	10. Device Available for	Evaluati	on? (Do not	i send to FD		
				[] Yes [_] No	[]] Re	timed to M	länufacturer	on:	(mm/sid/yyyy)
	(Continué on (18 200		11. Concomitant Medica	l Produc	ts and The	rapy Dates	(Exclude	
7. Other Relevant History, Including Pre	existing Medical Conditions (a.g., alle								
race, pregnancy, smoking and alconct u	se, hepelicrenel dystunction, etc.)							10	ontinuë on pag
				ENINDIAN REPOR				, ~	ionanioe on pag
·			Ĩ	1. Name and Address	*****			************	
			مسيل	Phone \$		Ema	ii Address		
	(Continue on)		-						-111-1 00-
Submission of a report does not personnel, user facility, importer,	distributor, manufacturer or p	nedical product		2. Health Professional?	3. Oces	spation		8	nitial Reporter Al Report to FDA
caused or contributed to the ever	st.			Yes No					Yes 🗌 No 🛛

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		allas av201311572		Page 2 Synaco omita			1	
Check Ons				teport Number	1. Type of Reportable E		278241(23)	2. If Follow-up, What Type
User Facility			.8897-20:		Cleath			
User Fecility or Imp					Serious Injury			Correction
					Malfunction			Response to FDA F
								Device Evaluation
					3. Device Evaluated by	Manufacturer	,	4. Device Manufacture Dat
					Not Returned to	Manufacturer	X	(mm/yyyy)
Contact Person			5. Phone N	umber 🚊	Yes Evst	tation Summar	/ Attached	
					No (Attach page	i ta explein why	702) or	5. Labeled for Single Use?
Date User Facility o Importer Bacame		7. Type of Repor	\$	8. Date of This Report (mm/d6/yyyy)	provide code:			Yes No
Aware of Event (mn	vldd/yyyy)	🛄 inital		(
Ŷ		Fallow-up #			6. Event Problem and E	valuation Cod	os (Refer ti	o coding manual)
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Age of Device	Patient				Device	(······
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	Device	·····	-]	Method		~	
Name and Advances and			L			L	L	[
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] Yes (mm/dd	Ancos	Hospita	RI RI	Diagnostic Facility				
	~~~~~	Home	Mane	Ambulatory	Conclusions	L]	~[	
Report Sent to Mar	nufacturer?	Nursing	3 Flome. ent Treatmer	Surgical Facility	7. If Remedial Action In	itisfed, Check	Туре	5. Usage of Device
] Yes	,,,	Facility		π.	Receil	Notification		initial Use of Device
No (mm/dd	****	Other:			Repair	Inspection		Reuse
. Nanufacturer Nam		1		(Specify)	Replace	Patient Mor	nitaring	Unknown
. ສາຍການຮະເພຊາ ກະສານ	suunmaäs				Reisheling	Modification		<ol> <li>If action reported to FDA un 21 USC 360I(f), list correctio</li> </ol>
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Paperwork Reduction Act (PRA) Staff PRAStaff@fce.hts:gov

The plate to send out the the time for reviewing instructions, searching existing data sources, gathering and meinteining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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FOIA CONFIDENTIAL TREATMENT REQUESTED

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Dudgenoscope Model ED-34907K/Serial Mu stated & user facility had reported th		é	·····,, ···			
appropriate cleaning and high level d	isinfection routine		ŝ		.::	 7
culturing on the device elevator produces results for carbapenem-resistant enter		8 jan				336 336
(CRE). This patient is at risk for pot				ः(C	ontinue on	page 3)
the organism."		1. Srand Rame	(11882)=V(012			
On 07/17/2015 Fentax sent an e-mail to		FERTAR				. Š
additional information. On 67/21/2019 informed PENTAX Medical that <u>it becam</u> e		2 Common Device Name Video Duedenoscop	*	25. P   FDT	rocode	1911 (1920) 1940 - 1940 1940 - 1940 - 1940 (1940)
positive culture results on Patient Informati		J. Manufacturar Nama; Ch MOYA Corporation	y and State		······································	<b>.</b>
the facility advised that it immediate scope from service, and 2 (two) [©] patie:		Takyo, Japan				
procedures with the scope were identia	fied. The event	4. Madel Ø			S. Operator	of Device
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indicates there was no patient injury.	•	Sorial S 🖉	Unique Identifier (l	101) <b>x</b>	C Other	: 🔊 ŝ
		A110592 6. If implanted, Give Date (	line in the second second	minut Ch	re Date (mm/r	defi
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iontvale, NJ 07645			3. Device Evaluated by	Stanutach mar 2	4. Device Manufacture Date
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, Contact Person	5. Phone N	kumber		ustion Summary Attached	TBD
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### (CONTINUATION PAGE) For use by user-facilities, importers, distributors, and manufacturers for MANDATORY reporting Page 3 of 3

FORM FDA 3500A (2/13) (continued) 8.5. Describe Event or Problem (continued)

MEDWATCH

Back to Hem B.5 B.6. Relevant Tests/Laboratory Data, Including Dates (continued) Back to item B.S B.J. Other Relevant History, including Pressisting Madical Conditions (e.g., ellargies, race, pregnancy, smoking and alcohol use, hepstic/anal dysfunction, stc.) (continued) Back to fizm B.7 Back to fiam D.11 Back to liam C.13 Concemitant Medical Products and Therapy Dates (Exclude bratment of event) (For continuation of C.10 and/or D.11/ please distinguish) Other Remarks Patient Code 3189 - Not Applicable; Patient Code 2645 - No Patient Thvolvement Device Code 1091 - Device Cleaning Issue Method Code 3263 - Actual Device Not Evaluated Results Code 3233 - Results Pending Completion Of Evaluation Conclusions Code 11 - Conclusion Not Yet Available-Eveluation In Progress

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## PENTAX PENTAX PENTAX DUODENOSCOPE

Back to Search Results

Model Number ED-3490TK Event Date 06/21/2013 Event Type Injury Event Description

Pt underwent an ercp procedure using a pentax ed-3490tk -a110084 side viewing duodenoscope. Pt developed a cre infection. Proper cleaning of scope confirmed as per company recommendations. Organism found under elevator on scope.

## Search Alerts/Recalls²³

New Search | Submit an Adverse Event Report²⁴

Brand NamePENTAX Type of DevicePENTAX DUODENOSCOPE Manufacturer (Section D)PENTAX **3 Paragon Drive** Montvale NJ 07645 MDR Report Key3252445 Report NumberMW5031083 **Device Sequence Number**1 Product CodeFDT²⁵ Report SourceVoluntary Reporter Occupation RISK MANAGER Type of ReportInitial **Report Date**07/23/2013 1 Device Was Involved in the Event **1** Patient Was Involved in the Event Date FDA Received07/23/2013 Is This An Adverse Event Report?No Is This A Product Problem Report? Yes Device Operator Health Professional Device MODEL NumberED-3490TK Device LOT NumberA110084 Was Device Available For Evaluation?Yes Is The Reporter A Health Professional?No Is this a Reprocessed and Reused Single-Use Device?Yes

Patient TREATMENT DATA Date Received: 07/23/2013 Patient Sequence Number: 1

### Links on this page:

- 1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
- 2. http://www.addthis.com/bookmark.php

### MAUDE Adverse Event Report: PENTAX PENTAX PENTAX DUODENOSCOPE

- 3. http://www.fda.gov/default.htm
- 4. http://www.fda.gov/MedicalDevices/default.htm
- 5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
- 6. /scripts/cdrh/devicesatfda/index.cfm
- 7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
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- 22. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
- 23. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm
- 24. https://www.accessdata.fda.gov/scripts/medwatch/
- 25. ../cfPCD/classification.cfm?start_search=&ProductCode=FDT

Page Last Updated: 10/31/2015

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U.S. Department of Health & Human Services

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- 21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
- 22. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
- 23. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm
- 24. https://www.accessdata.fda.gov/scripts/medwatch/
- 25. ../cfPCD/classification.cfm?start_search=&ProductCode=FDT

Allegheny General Hospital Pittsburgh, Pennsylvania



March 27, 2015

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,



Copies:

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)

5. Event Abated After Use Stopped or Dose Reduced? #1 Yes No Doesn'

Doesn'

Doesn't Apply

Doesn't Apply

(Continue on page 3)

5. Operator of Device

Lay User/Patient

(Continue on page 3)

Initial Reporter Also Sent Report to FDA

Yes No 🖌 Unk.

7. If Explanted, Give Date (mm/dd/yyyy)

✓ Health Professional

anufacturers	
	LIE#moorter Depar

Mfr Report # 2951238-2015-00127 UF/importer Report # FDA Use Only

			Form	Approved: OMB No. (	910-0291, Expires: 6 e OMB statement on
U.S. Department of Health and Human Services Food and Drug Administration	For use by us	er-facilities,	Mfr Report # 2	951238-2015-0	
<b>MEDWATCH</b>	importers, distributor for MANDATC	s and manufacturers DRY reporting	UF/importer Re		
FORM FDA 3500A (2/13)	Page 1 d	of 2			
A. PATIENT INFORMATION		C. SUSPECT PROD			FDA U
1. Patient Identifier 2.		1. Name (Give labeled stren			
		#1			
		#2		_	
B. ADVERSE EVENT OR PRODUCT PROBLEM	· · · · · · · · · · · · · · · · · · ·	2. Dose, Frequency & Rou	te Used	3. Therapy Dates ( from/to (or best e	(If unknown, give du estimate)
1. 🖌 Adverse Event and/or Product Problem (e.g.	, defects/malfunctions)	#1		#1	
2. Outcomes Attributed to Adverse Event (Check all that apply)		#2		#2	
	Permanent Damage	4. Diagnosis for Use (Indic	ation)	5. Event Stopp	Abated After Use ed or Dose Reduc
(mm/dd/yyyy)	nomaly/Birth Defect	#1			Yes No
	s (Important Medical Events)	#2 6. Lot #	7 Eve Dete		Yes No
Required Intervention to Prevent Permanent Impairment/D	amage (Devices)	#1	7. Exp. Date #1		Reappeared After
	eport (mm/dd/yyyy)	#1	#1	Reinte	roduction?
5. Describe Event or Problem	3/09/2015	#2 9. NDC# or Unique ID	#4	#1 [_] \	Yes No
Olympus received a Voluntary MedWatch th				#2	Yes No
patient's blood culture tested positive Klebsiella Pneumonia after undergoing ar Retrograde Cholangio-Pancreatography (ERC user facility noted that the patient had the this organism.	n Endoscopic CP)procedure.The	10. Concomitant Medical F	Products and The	rapy Dates (Exclude	treatment of event)
the this organism. Olympus has made multiple attempts to co facility for additional information by p writing with no results. No further info available at this time.	phone and in	D. SUSPECT MEDIC			Continue on page
available at this time.		2. Common Device Name	S EVIS EXER	A II Duodenvi	deoscope Procode
		Duodenvideoscope		FDT	
		3. Manufacturer Name, Cit OLYMPUS MEDICAL SYS 2951 Ishikawa-cho,	TEM CORPORATI		07, Japan
		4. Model # TJF~Q180V	Lot# N/A		5. Operator of De
		Catalog #		Date (mm/dd/yyyy)	Health Profe
		TJF-Q180V Serial #		N/A ntifler (UDI) #	Lay User/Pa
		UNK	N/A	antiner (ODI) #	
	Continue on page 3)	6. If Implanted, Give Date	(mm/dd/yyyy)		ve Date (mm/dd/yy)
6. Relevant Tests/Laboratory Data, Including Dates		N/A 8. Is this a Single-use Dev	ice that was Rep	N/A rocessed and Reuse	d on a Patient?
		Yes V No			
		9. If Yes to Item No. 8, Ent	er Name and Add	iress of Reprocesso	ır
		10. Device Available for E		-	
		🗌 Yes 🖌 No	Returned to M	Manufacturer on:	(mm/dd/yyyy)
	Continue on page 3)	11. Concomitant Medical I	Products and The	arapy Dates (Exclude	e treatment of event,
<ol> <li>Other Relevant History, Including Preexisting Medical Conc race, pregnancy, smoking and alcohol use, hepatic/renal dysfur</li> </ol>	litions (e.g., allergies, action, etc.)			(0	Continue on page
		E. INITIAL REPORT 1. Name and Address	ER		
		Allegheny General 320 East North Av Pittsburgh, PA 15	venue		
		Phone #	Em	ail Address	
( Submission of a report does not constitute an adm	Continue on page 3)	2. Health Professional?	3. Occupation	14	Initial Reporter Als
personnel, user facility, importer, distributor, manu caused or contributed to the event.	facturer or product	1 1	Risk Manage		Report to FDA

## **MEDWATCH**

Page 2 of 2

FDA	UŚE	ONLY	

FORM FDA 3500	A (2/13)	(continued	d)	Page	2 of <u>4</u>		
F. FOR USE BY	USER FA	CILITY/IM	PORTER (D	evices Only)	H. DEVICE MANU	FACTURERS ONLY	
1. Check One			2. UF/Importer R		1. Type of Reportable I		2. If Follow-up, What Type?
User Facility	🗌 Impo	I			Death		
3. User Facility or Imp	·						
of Ooor Facinity of hisp		Aunoss			Serious Injury		Additional Information
					Malfunction		Response to FDA Request
							Device Evaluation
					3. Device Evaluated by	Manufacturer?	4. Device Manufacture Date
					Not Returned to		(mm/yyyy)
4. Contact Person			5. Phone N	umber		uation Summary Attached	Unk
							5. Labeled for Single Use?
6. Date User Facility o	r	7. Type of Re		8. Date of This Report	provide code:	ə to explain why not) or	c. Easered for Single Deer
Importer Became	1		,port	(mm/dd/yyyy)			Yes 🗸 No
Aware of Event (mn	(aayyyyy)	Initial					
		Follow-u	p#			Evaluation Codes (Refer to c	oding manual)
9. Approximate	10. Event F	Problem Code	es (Refer to codi	ng manual)	Patient Code	1735 -	-
Age of Device	Patient		¬		Device		
	Code		-	-	Code	1091 - 2	2303 -
	Device						
	Code				Method	L	
11. Report Sent to FD/	A7	12. Locatio	n Where Event	Occurred	Results		
Yes		Hos	spital	Outpatient	Nesults		
No (mm/dd	(yyyy)	Hor	ne	Diagnostic Facility	Conclusions	67 - 92	
13. Report Sent to Mar	nufacturer?	- Nur	sing Home	Ambulatory Surgical Facility	· · · · · ·		
			patient Treatmer	• •	7. If Remedial Action In	altiated, Check Type 8.	Usage of Device
Yes(mm/dd	(vvv)	Fac	•		Recall	Notification	Initial Use of Device
No (Insta		Oth	er:	(Specify)	🔄 Repair	Inspection	Reuse
14. Manufacturer Nam	e/Address			(Opecky)	Replace	Patient Monitoring	Unknown
					Relabeling		If action reported to FDA under 21 USC 360I(f), list correction/
						Adjustment	removal reporting number:
					Other:		
					10. 🗸 Additional Man	ufacturer Narrative ar	nd / or 11. Corrected Data
G. ALL MANUFA	CTURER	S					port has not yet been
1. Contact Office (and			Devices)	2. Phone Number			on. If any additional
Name	-					comes available the	
				3. Report Source	supplemented ad	cordingly.	
Address				(Check all that apply)			
OLYMPUS AMERIC	A TNC			Foreign	As part of our	invection with	h this mensul
2400 Ringwood				Study		investigation with	list (ESS) performed an
San Jose, CA 9				Literature	In-Service and	trained staff on	TJF-180V reprocessing at
			+		the user facil:	ty on 05/24/2015.	The ESS observed that
Email Address				Health Professional		ty was not follow	
A Data Decet		6		↓ ↓ User Facility	reprocessing of	auodenvideoscope	s correctly. Freshwater pe, single-use items
<ol> <li>Date Received by Manufacturer (mm/d)</li> </ol>	id/yyyy)	5.		Company	were being used	to clean multiple	e scopes and reusable
03/09/20		(A)NDA #		Representative			h level disinfected per
6. If IND, Give Protoco		IND #		Distributor	each use. Addit	ionally, this acc	ount uses a third party
S. IT IND, GIVE Protoco	H #	BLA #		Other:		d was unsure of th	e serial number of the
		DMA/			scope.		
7. Type of Report		510(k) #	K080403				
(Check all that apply)		Combinati	on				
5-day 🗹 30-da	•	Product	Yes				
7-day Perio		Pre-1938	Yes				
☐ 10-day 🗸 Initial		OTC Prod	uct TYes				
15-day Follo	w-up #					,	
9. Manufacturer Report	rt Number	8. Adverse	e Event Term(s)		11		
2951238-2015-00127							
	-						
			•	k Reduction Act of 1995.	Department of Health an Food and Drug Administ		OMB Statement: "An agency may not
minutes per response, in				en estimated to average 66 searching existing data	Office of Chief Informatio	n Officer	conduct or sponsor, and a person is not required to respond to, a collection of

sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

# Boca Raton Regional Hospital Boca Raton, Florida

U.S. Department of Health and Human Services Food and Drug Administration	<b>-</b> (		Mfr Report #:	2951238-2015-00184	
MEDWATCH	For use by user importers, distributors	-facilities,	UF/Importer Report #:		
FDA eSubmitter Generated Form 3500A	for MANDATOI	RY reporting	Form Code:		
A. PATIENT INFORMATION					
1. Patient Identifier (in confidence)				4. Weight	
				4. WEIGHT	
<b>B. ADVERSE EVENT OR PRODUCT PROBLEM</b>		· ·			
1. [X] Adverse Event and/or [] Product Pro	blem (e.g., defects/malfun	ctions)			
2. Outcomes Attributed to Adverse Event (Checked a	all that apply)				
[] Death [] Life-threatening			y or Permanent		
[] Hospitalization - initial or prolonged		(V) Other S	ital Anomaly/Birt erious (Importan	h Defect t Medical Events)	
[] Required Intervention to Prevent Permanen	nt impairment/Damage (D	evices)			
3. Date of Event (mm/dd/yyyy)		4. Date of this Report (n	nm/dd/yyyy)		
06/11/2014	· .	04/14/2015			
5. Describe Event or Problem					
Olympus was informed that a total of nine Klebsiella pneumoniae, after having under However only six of those patients used a underwent a procedure using either a Fuji	n Olympus duodopovid	trograde cholanglop			
Olympus followed up with the user facility and was informed that they have implemented a double (2x's) with high level (HLD) disfectant in the AER disinfection process for all duodenovideoscopes. It was reported by the user facility that since mid 2014, they began to monitor and randomly cultured all their duodenovideoscopes after confirming five patient infections of CRE-KP ranging from August 08, 2014 to December 12, 2014 after each had undergone a ERCP procedure. The inItial five patient infections with CRE-KP were confirmed utilizing test methods ranging from sputum, blood, urine, liver aspirate, and bile drainage. The patients were treated with antibiotics. It was reported that there were no further issues with the duodenovideoscopes testing positive until a sixth patient tested positive for Extended Spectrum Beta-Lactamase (ESBL) strain following the March 16, 2015 ERCP procedure using the same duodenovideoscope (s/n: 2102101). On March 21, 2015 the duodenovideoscope cultured (2x's)HLD in the AER disinfection cycle. The duodenovideoscope was re-cultured and showed no growth. The duodenovideoscope was placed back in service on March 24, 2015. The user facility said they will continue to monitor and complete random testing to control the issue in-house so no further issues occur.					
This is the first of six reports.					
6. Relevant Tests/Laboratory Data, Including Dates	····				
Blood and urine test on 12/12/2014					
7. Other Relevant History, Including Preexisting Medi	ical Conditions (e.g., allergie	s, race, pregnancy, smoki	ng and alcohol use	, hepatic/renal dysfunction, etc.)	
Pancreatic carcinoma					
C. SUSPECT PRODUCT(S)					
Section C is not applicable to devices.			• .		
D. SUSPECT MEDICAL DEVIÇE					
1. Brand Name Olympus EVIS EXERA II DUODENOVIDEOSCO	DE	2. Common Device Nam			
3. Manufacturer Name, City and State		Duodenovideoscope	r		
OLYMPUS MEDICAL SYSTEM CORPORATION	J	4. Model # TJF-Q180V		Catalog # TJF-Q180V	
2951 Ishikawa-cho,		Serial #			
Hachloji-shi, Tokyo, 192-8507, Japan, JA		2102101		Lot #	
		Expiration Date (mm/dd)	haand	Other#	
				Other #	
5. Operator of Device		6. Implanted Date (mm/c	dd/vvvv)	7. Explanted Date (mm/dd/yyyy)	
Health Professional		hanne - and hanne			
<ul> <li>8. Is this a Single-Use Device that was reprocessed at</li> <li>( ) Yes (•) No ( ) No Information</li> </ul>	nd Reused on a Patient?		I		
9. Reprocessor Name and Address		40 Davies Assett 11 -	- Phanella, 44		
		<ul> <li>10. Device Available for</li> <li>() Yes</li> <li>(•) No</li> <li>() No Information</li> <li>[] Returned to Ma</li> </ul>		not send to FDA)	
······					

U.S. Department of Health and Human Services Food and Drug Administration	Farmer to a	6 W.	Mír Report #:	2951238-2015-00184	
MEDWATCH	For use by user importers, distributors		UF/Importer Re		
DA eSubmitter Generated Form 3500A	for MANDATORY reporting		Form Code:		
11. ConComitant Medical Products and Therapy Date Medivator DSD-Edge Pentax Duodenovideoscope Fuji Duodenovideoscope	s (Excludes treatment of eve	nt)	L		
E. INITIAL REPORTER					
1. Name and Address		2. Health Professional?			
Boca Raton Regional Hospital, Inc.		(•) Yes ( ) No	() No Infor	mation	
800 Meadows Road Boca Raton, FL 33486-2368, US		3. Occupation Physician			
		4. Initial Reporter Also S	ent Report to F	DA?	
		() Yes () No	(•) Unknow	n () No Information	
F. FOR USE BY USER FACIL/TY/IMPORTER (De I. User Facility or Importer	evices Only)				
() User Facility () Importer		2. User Facility/importer	Number		
3, 4, and 5. User Facility or Importer Name/Address, C Phone Number	Contact Person, and	6. Date UF/Importer Bec	ame Aware of E	vent (mm/dd/yyyy)	
		7. Type of Report () Initiai () Fo	llow-up		
		8. Date of This Report (	nm/dd/yyyy)	9. Approximate Age of Device	
0. Event Problem Codes (Refer to coding manual)		14 Manufacturer Name	Address		
Patient Code(s): 1735		14. Manufacturer Name/Address CA, US			
Device Code(s): 2303					
1. Report Sent to FDA?					
() Yes () No () No Information					
12. Location Where Event Occurred					
13. Report Sent to Manufacturer?					
() Yes () No () No Information		÷			
G. ALL MANUFACTURERS					
I, 2. Contact Office - Name/Address/Phone Number Olympus America 2400 Ringwood Ave San Jose, CA 95131, US		1, 2. (Continued) Manuf	acturing Site Ad	ldress/Phone for Dovices	
. Report Source (Check all that apply)		4. Date Received by Ma	nufacturer (mm/	/dd/yyyy)	
[ ] Foreign       [X] Health Profe         [ ] Study       [X] User Facility					
[] Study     [X] User Facility       [] Literature     [X] Company R       [] Consumer     [] Distributor		5. PMA/510(k) K080403		· · · · · · · · · · · · · · · · · · ·	
[] Other		6. If IND, Give Protocol	#		
7. Type of Report []5-day [X] Initial [] Follow-up		8. Adverse Event Term(	s)	9. Manufacturer Report Number 2951238-2015-00184	
I. DEVICE MANUFACTURERS ONLY					
( ) Death     [ ] Correction       (•) Serious injury     [ ] Addition       ( ) Malfunction     [ ] Resp	lonal Information onse to FDA Request e Evaluation	3. Device Evaluated by [] Not Returned to () Yes [] Eva (•) No	Manufacturer		

## OCA_0000428

Food and Drug Administration	g Administration     For use by user-facilities,       TCH     importers, distributors and manufacturers		2951238-2015-00184
MEDWATCH importers, distri			UF/Importer Report #: Form Code:
<ul> <li>4. Device Manufacture Date (mm/dd/yyyy)</li> <li>5. Labeled for Single Use? <ul> <li>() Yes</li> <li>() No</li> <li>() No</li> </ul> </li> </ul>	6. Evaluation Codes (R Method Code(s): 332 Result Code(s): Conclusion Code(s):	20	nuai)
7. If Remedial Action Initiated, Check Type          [] Recail       [] Notification         [] Repair       [] Inspection         [] Replace       [] Patient Monitoring         [] Relabeling       [] Modification/Adjustment         [] Other       [] Action	8. Usage of Device () Initial Use of D () Reuse () Unknown () No Information		9. If action reported to FDA under 21 USC 3601(f), list correction/removal reporting number
10. [X] Additional Manufacturer Narrative and/or 11. [ ] Correct The device referenced in this report has been returned to d independent laboratory for further testing. Once returned a exact cause of the user's experience could not be conclusi additional and significant information becomes available in As part of our investigation with this report, an Endoscopy facility's reprocessing practices. During the on-site visit, se pre-cleaning, manual cleaning w/HLD, Rinsing, Alcohol flu using a Medivator DSD-Edge AER. It was also reported th removing from the AER. The customer was informed that 1 noted that the user facility was not using a MH-856 (suction Please cross-reference the associated complaints: 2951238-2015-00185, 2951238-2015-00186, 2951238-20	Olympus for evaluation. Ho a physical evaluation will be lively determined at this time ater. Support Specialist (ESS) v everal reprocessing practice ish but were not demonstra the customer sometimes the scopes need to be hung in cleaner adapter), as reco	isited the use as were discus ted as the cus a lay down the g immediately mmended in t	r facility to observe the user seed such as manual cleaning, stomer stated that they are ir scopes colled up after after the HLD process. It was the instruction manual.
No files attached.			

**Carolinas Medical Center, Charlotte North Carolina**  **U.S. Department of Health and Human Services** Food and Drug Administration

Food and Drug Administration	For use by user-facilities,	
MEDWATCH	importers, distributors and manufacturers	UF/Importer Report #:
FDA eSubmitter Generated Form 3500A	for MANDATORY reporting	Form Code:

Mfr Report #:

2951238-2015-00254

A. PATIENT INFORMATION		
1. Patient Identifier (In confidence)		4. Weight
B. ADVERSE EVENT OR PRODUCT PROBLEM		
1. [X] Adverse Event and/or [] Product Problem (e.g., defects/malfund	ctions)	
2. Outcomes Attributed to Adverse Event (Checked all that apply)		
<ul> <li>[x] Death</li> <li>[ ] Life-threatening</li> <li>[ ] Hospitalization - initial or prolonged</li> <li>[ ] Required Intervention to Prevent Permanent impairment/Damage (Detection of the provided of t</li></ul>	<ul> <li>[ ] Disability or Permanent</li> <li>[ ] Congenital Anomaly/Birl</li> <li>[ ] Other Serious (Importane)</li> </ul>	th Defect
3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy) 05/14/2015	
5. Describe Event or Problem		······
In an article published on May 15, 2015, it was reported that a pa resistant Enterobacteriacaea (CRE) infection following an ERCP	tient at a medical center died in 20 procedure using an Olympus duod	13 as a result of carbapenem- lenoscope.
Olympus followed up with the user facility in an effort to obtain ad results after multiple inquiries.	ditional information regarding the r	reported event, but with no
6. Relevant Tests/Laboratory Data, Including Dates		
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergie	s, race, pregnancy, smoking and alcohol us	e, hepatic/renal dysfunction, etc.)
C. SUSPECT PRODUCT(S)		
Section C is not applicable to devices.		
D. SUSPECT MEDICAL DEVICE	· · · · · · · · · · · · · · · · · · ·	
1. Brand Name	2. Common Device Name	
EVIS EXERA II Duodenovideoscope	Duodenoscope, Product Code: FDT	
3. Manufacturer Name, City and State	4. Model #	Catalog #
Olympus Medical System Corporation	TJF-Q180V	TJF-Q180V
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, JA	Serial #	Lot #
	Unk	N/A
	Expiration Date (mm/dd/yyyy)	Other #
5. Operator of Device Health Professional	6. Implanted Date (mm/dd/yyyy)	7. Explanted Date (mm/dd/yyyy)
<ul> <li>8. Is this a Single-Use Device that was reprocessed and Reused on a Patient?</li> <li>( ) Yes (•) No ( ) No Information</li> </ul>		
9. Reprocessor Name and Address	<ul> <li>10. Device Available for Evaluation? (Details)</li> <li>( ) Yes</li> <li>(•) No</li> <li>( ) No Information</li> <li>[ ] Returned to Manufacturer</li> </ul>	o not send to FDA)
11. ConComitant Medical Products and Therapy Dates (Excludes treatment of eve	nt)	
E. INITIAL REPORTER		
1. Name and Address	2. Health Professional? (•) Yes () No () No Info	rmation
Carolinas Medical Center		
1000 Blythe Blvd. Charlotte, NC 28203-5871, US	3. Occupation Risk Manager	
Email:Unk	4. Initial Reporter Also Sent Report to F () Yes () No (●) Unknov	
F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)	• · · · · · · · · · · · · · · · · · · ·	
1. User Facility or Importer	2. User Facility/Importer Number	

For use by user-facilities,
importers, distributors and manufacturers
for MANDATORY reporting

Mfr Report #: 2951238-2015-00254 UF/Importer Report #:

MEDWATCH		ors and manufacturers		•	
FDA eSubmitter Generated Form	3500A for MANDAT	ORY reporting	Form Code:		
() User Facility () Importe	)r				
3, 4, and 5. User Facility or Importer Phone Number	Name/Address, Contact Person, and	6. Date UF/Importer Be	ecame Aware of	Event (mm/dd/yyyy)	
		7. Type of Report		·····	
		() Initial () F	Follow-up		
		8. Date of This Report	(mm/dd/yyyy)	9. Approximate Age of Device	
10. Event Problem Codes (Refer to co	oding manual)	14. Manufacturer Nam	e/Address	· · · · · · · · · · · · ·	
Patient Code(s): 1735 - 1802 Device Code(s): 2303					
11. Report Sent to FDA?					
() Yes () No () No Ir	Iformation				
12. Location Where Event Occurred					
13. Report Sent to Manufacturer?					
()Yes ()No ()Nolr	Iformation				
G. ALL MANUFACTURERS					
1, 2. Contact Office - Name/Address/	Phone Number	1, 2. (Continued) Man	ufacturing Site A	ddress/Phone for Devices	
Olympus America, Inc.					
2400 Ringwood Avenue					
San Jose, CA 95131, US					
3. Report Source (Check all that apply	•	4. Date Received by M	lanufacturer (mn	n/dd/yyyy)	
	] Health Professional ] User Facility	05/14/2015 5. PMA/510(k)			
[X] Literature [	Company Representative				
[X] Consumer [ [] Other	] Distributor	K080403			
		6. If IND, Give Protoco	ol #		
7. Type of Report		8. Adverse Event Terr		9. Manufacturer Report Number	
[] 5-day [x] Initial [] F	⁻ ollow-up	o. Auverse Event Terr	11(5)	2951238-2015-00254	
H. DEVICE MANUFACTURERS (	-				
1. Type of Reportable Event	2. If Follow-up, What Type?	3. Device Evaluated b	y Manufacturer?		
(•) Death	[] Correction	[] Not Returned	to Manufacture	r	
<ul> <li>( ) Serious Injury</li> <li>( ) Malfunction</li> </ul>	[ ] Additional Information [ ] Response to FDA Request	() Yes [] Ev (●) No	valuation Sumn	nary Attached	
() No Information	[ ] Device Evaluation	(•) NO			
·	[ ] No Information	····			
4. Device Manufacture Date (mm/dd/y	<i>יyyy</i> )	6. Evaluation Codes (	Refer to coding m	anual)	
5 Labolad for Circula U.v.O		Method Code(s): Result Code(s):			
5. Labeled for Single Use?	oformation	Conclusion Code(s	s): 67 - 92		
7. If Remedial Action initiated, Check		8. Usage of Device	·	9. If action reported to FDA under 21	
	] Notification	() Initial Use of I	Device	USC 360i(f), list correction/removal reporting number	
-	] Inspection	(•) Reuse			
[] Replace [ [] Relabeling [	<ul> <li>Patient Monitoring</li> <li>Modification/Adjustment</li> </ul>	() Unknown () No Informatio	n		
[] Other					
10. [X] Additional Manufacturer N	Varrative and/or 11. [ ] Corrected [	Data			
No device was returned to O	lympus for evaluation. The exact	cause of the source of	f the infection	is unknown and the exact	
cause of death is unknown.	This report will be updated accord	ingly if additional infor	mation becon	nes available at a later time.	

**MEDWATCH** FDA eSubmitter Generated Form 3500A For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting Mfr Report #:

2951238-2015-00254

UF/Importer Report #:

ng Form Code:

Please cross reference MFR. Report Numbers: 2951238-2015-00258, 2951238-2015-00259, and 2951238-2015-00281.

### File Attachments

No files attached.

U.S. Department of Health and Human Services			Mfr Report #:	29	51238-2015-00281
Food and Drug Administration	For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting		UF/Importer Report #:		
MEDWATCH			Form Code:		
FDA eSubmitter Generated Form 3500A					
A. PATIENT INFORMATION					
1. Patient Identifier (In confidence)	2. Age at Time of Event, D	ate of Birth	3. Sex No Informa	tion	4. Weight
B. ADVERSE EVENT OR PRODUCT PROBLEM					
1. [x] Adverse Event and/or [] Product Pro	blem (e.g., defects/malfun	octions)			
2. Outcomes Attributed to Adverse Event (Checked a	ll that apply)				
[X] Death       [] Disability or Permanent Damage         [] Life-threatening       [] Congenital Anomaly/Birth Defect         [] Hospitalization - initial or prolonged       [] Other Serious (Important Medical Events)         [] Required Intervention to Prevent Permanent impairment/Damage (Devices)					/ents)
3. Date of Event (mm/dd/yyyy)		4. Date of this Report (	mm/dd/vvvv)		
		05/14/2015			
5. Describe Event or Problem					
Olympus became aware of a news article carbapenem-resistant Enterobacteriacaea hospital; three acquired it in the hospital, a how the three became infected in the hos information regarding the reported event,	a (CRE) in the first mon and one died. The cau pital. Olympus followed	ths of 2015. Of thos se of death was not d up with the user fa	e, 15 had CRE reported. No c	E upon adm details were	ission to the reported about
In an article published on May 15, 2015, it result of CRE infection following an ERCP an Olympus product was allegedly associ submit a report for the three CRE cases d duodenoscope may have been associated earlier this year.	Procedure using an O ated with CRE infection liscussed in the Februa	lympus duodenosco n at the medical cent ny 2015 article base	pe. Because t ter in 2013, Oly d on the possil	he May 15 /mpus has pility that ar	article reports that determined to n Olympus
6. Relevant Tests/Laboratory Data, Including Dates					
·	· · · · · · · · · · · · · · · · · · ·		· · · · · · · · · · · · · · · · · · ·		
7. Other Relevant History, Including Preexisting Med	lical Conditions (e.g., allergi	es, race, pregnancy, smol	king and alcohol us	se, hepatic/ren	al dysfunction, etc.)
C. SUSPECT PRODUCT(S)		<u>.</u>			
Section C is not applicable to devices.					
D. SUSPECT MEDICAL DEVICE		· · · · · · · · · · · · · · · · · · ·			
1. Brand Name		2. Common Device Na		_	
EVIS EXERA II Duodenovideoscope		Duodenoscope, Pro	oduct Code: FDT		
3. Manufacturer Name, City and State		4. Model #		Catalog #	
Olympus Medical System Corporation		Unk		Unk	
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, JA		Serial #		Lot #	
		Unk		N/A	
		Expiration Date (mm/c	ld/yyyy)	Other #	
5. Operator of Device Health Professional		6. Implanted Date (mn	n/dd/yyyy)	7. Explante	d Date (mm/dd/yyyy)
8. Is this a Single-Use Device that was reprocessed () Yes (•) No () No Information	and Reused on a Patient?	<b>1</b> .,			
9. Reprocessor Name and Address		10. Device Available f	or Evaluation? (D	o not send to	FDA)
		<ul> <li>() Yes</li> <li>(•) No</li> <li>() No Informatio</li> <li>[] Returned to M</li> </ul>	n		, ,
11. ConComitant Medical Products and Therapy Dat	es (Excludes treatment of ev		······································	_, <u></u>	
E. INITIAL REPORTER	1	· · · · · · · · · · · · · · · · · · ·			
1. Name and Address		2. Health Professiona	12		
		(•) Yes () N		rmation	
Carolinas Medical Center					
1000 Blythe Blvd.		3. Occupation			

U.S. Department of Health and Human Services Food and Drug Administration	6 H.	Mfr Report #: 2951238-2015-00281			
in the by use		UF/Importer Report #:			
MEDWATCH         Importers, distributors           FDA eSubmitter Generated Form 3500A         for MANDATOR					
Charlotte, NC 28203-5871, US	Risk Manager	<u></u>			
Email:Unk	4. Initial Reporter Also	Sent Report to FI	DA?		
	() Yes () No	(•) Unknow	n () No Information		
F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)					
1. User Facility or Importer () User Facility () Importer	2. User Facility/Import	er Number			
3, 4, and 5. User Facility or Importer Name/Address, Contact Person, and	6. Date UF/importer B	came Aware of E	vent (mm/dd/vvvv)		
Phone Number					
	7. Type of Report				
	() Initial () F	ollow-up			
	8. Date of This Report	(mm/dd/yyyy)	9. Approximate Age of Device		
10. Event Problem Codes (Refer to coding manual)	14. Manufacturer Nam	e/Address			
Patient Code(s): 1735 - 1802					
Device Code(s): 2303	4				
11. Report Sent to FDA? () Yes () No () No Information		•			
12. Location Where Event Occurred	-				
13. Report Sent to Manufacturer?	<b>- </b> .				
() Yes () No () No Information					
G. ALL MANUFACTURERS 1, 2. Contact Office - Name/Address/Phone Number					
Olympus America, Inc. 2400 Ringwood Avenue San Jose, CA 95131, US					
3. Report Source (Check all that apply) [ ] Foreign [ ] Health Professional	4. Date Received by N 05/14/2015	lanufacturer (mm/	dd/yyyy)		
[] Study     [] User Facility       [x] Literature     [] Company Representative	5. PMA/510(k)				
[X] Consumer [] Distributor	Unk				
[ ] Other	6. If IND, Give Protoco	bl #			
7. Type of Report	8. Adverse Event Terr	n(s)	9. Manufacturer Report Number		
[] 5-day [x] Initial [] Follow-up			2951238-2015-00281		
H. DEVICE MANUFACTURERS ONLY					
1. Type of Reportable Event     2. If Follow-up, What Type?       (•) Death     []] Correction	3. Device Evaluated b	-			
( •) Death [] Correction [] Additional Information	[] Not Returned () Yes [] E		arv Attached		
() Malfunction [] Response to FDA Request	(•) No				
( ) No Information [ ] Device Evaluation [ ] No Information					
4. Device Manufacture Date (mm/dd/yyyy)	6. Evaluation Codes (	Refer to coding ma	nual)		
	Method Code(s):	-			
5. Labeled for Single Use?	Result Code(s):				
() Yes (•) No () No Information	Conclusion Code(s	6): 67 - 92			
7. If Remedial Action Initiated, Check Type	8. Usage of Device		9. If action reported to FDA under 21 USC 360i(f), list correction/removal		
[] Recall     [] Notification       [] Repair     [] Inspection	<ul><li>( ) Initial Use of</li><li>(•) Reuse</li></ul>	Device	reporting number		
L					

MEDWATCH importers, distributors and manufacturers	UF/Importer Repo	ort #:
FDA eSubmitter Generated Form 3500A       for MANDATORY reporting         [] Replace       [] Patient Monitoring       ( ) Unknown         [] Relabeling       [] Modification/Adjustment       ( ) No Information	Form Code:	
[] Relabeling [] Modification/Adjustment () No Information		
No device was returned to Olympus for evaluation. The exact cause of the source of th cause of death is unknown. This report will be updated accordingly if additional information Please cross reference Mfr. Report Number: 2951238-2015-00254, 2951238-2015-00	ation becomes	available at a later time.
File Attachments		
No files attached.		

# Cedars-Sinai Medical Center Torrance, California



March 20, 2015

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event. Any further correspondence may be directed to my office.

• ;

Sincerely,



Copies:

OCA_0001226

Form Approved: OMB	No. 0910-0291.	Expires: 8/30/201#
( on opposition of the second	Sen CMR etc	lement on reveal

				Form A	pproved: OakB NO. C	e OMB statem	ent on reverse
	U.S. Department of Health and Human Services Food and Drug Administration		er-facilities,	Mfr Report # 29	51238-2015-	0094	
	MEDWATCH	importers, distributors for MANDATC	RY reporting	UF/importer Rep	ort #		
	FORM FDA 3500A (2/13)	Page 1 d	of ²				FDA Use Only
	A. PATIENT INFORMATION		C. SUSPECT PRODU	ICT(S)			DA USU UNY
	1. Patlent Identifier 2. Age at Time	3. Sex 4. Weight	1. Name (Give labeled streng	ih & mfr/labeler)			
	of Event:	Femate lbs	#1				
	Date	Male kas	#2				
	In confidence of Birth: B. ADVERSE EVENT OR PRODUCT PROBL	Ryo	2. Dose, Frequency & Rout	e Used	<ol> <li>Therapy Dates from/to (or best</li> </ol>	(if unknown, g estimate)	vive duration)
		(e.g., delects/maifunctions)	#1		#1		
	2. Outcomes Attributed to Adverse Event (Check all (hat apply)		#2		#2		
		y or Permanent Damage	4. Diagnosis for Use (Indica	alion)	Stop	t Abated Afte	r Use Reduced?
	(mm/dd/yyyy)	ital Anomaly/Birth Defect	#1		#1 🗔	Yes 🛄 No	Doesn' Apply
		erious (Important Medical Events)	#2	7 Euro Data	#2	Yes No	Doesn'
	Required Intervention to Prevent Permanent Impairm	ent/Damage (Devices)	6. Lot #	7. Exp. Date #1	8. Eve	t Reappeared	Apply
		his Report (mm/dd/yyyy)	#1		Reir	troduction?	Doesn'
	08/01/2014-02/28/2015	03/04/2015	#2 9. NDC# or Unique ID	#2	#1 [	Yes 🗌 No	Apply
	5. Describe Event or Problem Olympus was informed that four patie		8. NDD# Of Onique iD		#2	Yes 🗌 No	Doesn' Apply
	infected by a "drug resistant organi resistant enterobacteriaceae (CRE) f duodenoscope in use from August 2014	rom one Olympus to mid-February	10. Concomitant Medical	Products and The	rapy Dates (Exclu	le treatment of	event)
BLACK INK	2015. It was further reported that o infected patient's expired. The caus unknown. However, it was reported th	e of death is				(Continue o	n nora 91
×	unrelated to a CRE infection.		D. SUSPECT MEDI	CAL DEVICE		(ooninide D	n page Sj
Ϋ́	Olympus made multiple attempts to ob		1 Deeped Name	s Duodenovi	deoscope		
88	information via telephone and in wri success.	ting, but with no	2. Common Device Name			. Procode	
S			Duodenovideos cop 3. Manufacturer Name, C	8	P	OG	
PLEASE TYPE OR USE	This is one of four reports.		3. Manufacturer Name, C OLYMPUS MEDICAL SY 2951 Ishikawa-cho,	STEM CORPORAT Hachioji-shi	10N , Tokyo, 192-	-	
Ξ		:	4. Model# Unk	Lot#			or of Device
B		· · · · ·	Catalog #		n Date (mm/dd/yy)	v)	h Professiona
EA			Unk		N/A entifler (UDI)#		Jser/Patient
Ч	· · ·		Serial # Unk	Ontque la	enuner (001)#		
		(Continue on page 3)	6. If Implanted, Give Date	(mm/dd/yyyy)	7. If Explanted	, Give Date (mr	n/dd/yyyy)
	6. Relevant Tests/Laboratory Data, Including Dates	(continue on page of	N/A 8. Is this a Single-use De	vice that was Re	N/A processed and Re	used on a Pati	ent?
			Yes 🖌 No				
			9. If Yes to Item No. 8, E	nter Name and Ad	dress of Reproce	5507	
	•						
			10. Device Available for	•			
			Yes 🖉 No	Returned to	Manufacturer on:	(mm/dd/	yyyy)
		(Continue on page 3)	11. Concomitant Medica	Products and T	herapy Dates (Ex	clude treatment o	of event)
	<ol> <li>Other Refevant History, Including Preexisting Medice race, pregnancy, smoking and alcohol use, hepatic/renal</li> </ol>	I Conditions (e.g., allergies, dysfunction, etc.)					
						(Continue o	on page 3)
			E. INITIAL REPOR	TER			
	and the second		1. Name and Address			•	
			Cedars-Sinai Me		r		
			4100 W. 190th S Torrance, CA 90				
					mall Address		
		(Continue on page 3)	Phone #	d	mall Address		
	Submission of a report does not constitute ar	admission that medical	2. Health Professional?	3. Occupation		4. Initial Repo	orter Also Se
	personnel, user facility, importer, distributor, caused or contributed to the event.	manufacturer or product	Yes 🗌 No	Risk Manag	jer	Report to F	™DA ]No [[]Uni

FDA USE ONLY

MEDW								
FORM FDA 3500A				Page 2				
F. FOR USE BY U	JSER FA						ACTURERS ONLY	
1. Check One			Amporter Re	port Number		Reportable Eve	ont	2. If Follow-up, What Type?
User Facility								
3. User Facility or Impo	orter Name	Address				atious injury alfunction		Additional Information
						allunction		Device Evaluation
						Evaluated by M		4. Device Manufacture Date (mm/yyyy)
4. Contact Person			5. Phone Nu	mhar		ot Returned to M	lenutaclurer Ition Summary Attached	Unk
4. CONTROL FORSON		1	o. Phone Mu	mbar		<b>1</b> 1	io explain why not) or	5. Labeled for Single Use?
6. Date User Facility or	, 1	7. Type of Report	t	8. Date of This Report		rovide code;		Yes VNo
Importer Became Aware of Event (mm)	(dd/yyyy)	[ ] Initial		(mm/dd/yyyy)				
		Follow-up#			6. Event	Problem and Ev	aluation Codes (Refer to	coding manual)
9. Approximate	10. Event	Problem Codes (		n menuel)		Patient Code	1802 -	1735 -
Age of Device	Patient		(	······································		Device		0000
	Code		·[			Code	1120 -	2303 -
	Device Code	-	•	-		Method		
11. Report Sent to FDA	- <b>-</b>	12. Location W	here Event (	Decurred	11			
Yes		Hospita		Cipatient		Results	L	
Mo (mm/dd/	(yyyy)	Home		Disgnostic Facility	11	Conclusions	20 - 92	
13. Report Sent to Man	ufacturer	Nursing	Home	Ambulatory Surgical Facility	7. If Rem	edial Action ini	tlated, Check Type	8. Usage of Device
Yes		Outpati Facility	ent Treatmer	ıt		Recall [	Notification	Initial Use of Device
No (mm/dd/	(yyyy)	Olher:				Repair [		Reuse
14. Manufacturer Name				(Specify)		Replace [	Patient Monitoring	Unknown
14. Wattchacturer Wallin	e/Addless				ΙĒ	Relabeling [	Modification/	9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:
						Other:	Adjustment	removal reporting number:
						Outer		
					10 100		ufacturer Narrative	and / or 11. Corrected Data
G. ALL MANUFA	CTURE	20						and/or 11. Corrected Data report has not been
1. Contact Office (and			lces)	2. Phone Number	retur	ned to oly	mpus for evaluat	tion. The exact cause of
Namo	_		,		the r	eported ev	ent could not be	e conclusively determined
Address				3. Report Source (Check all that apply)	- at th	is time. H alist (ESS	lowever, an Olymp has been sched	ous Endoscopy Support duled to visit the site to
				Foreign	perfo	rm a demon	stration of Oly	npus recommended
OLYMPUS AMERICA 2400 Ringwood A	A, INC			Study	repro	cessing pr	actice.	
San Jose, CA 9				Literature	If ad	ditional i	nformation become	mes available at a later
Email Address			1	Consumer	time,	this repo	ort will be supp	lemented.
Lines Plug 055				Health Professional	Pleas	e cross re	eference mfr. re	port numbers:
4. Date Received by	debases?	5,		User Facility	29512	38-2015-00	095, 2951238-20	15-00140, and
Manufacturer (mm/c 03/04/2		(A)NDA#		Company Representative	29512	38-2015-00		
6. If IND. Give Protoco		IND#		Distributor				
	<i>ν</i> . π	BLA#		Other:				
7. Type of Report		- PMAV			-			
(Check all that apply)	)	510(k) #		·				
□ 5-day 🗹 30-da	•	Combination Product	🗌 Yes					
7-day Perio		Pre-1938	Yes		-			
10-day 📝 initia		OTC Product	Yes	· .	_			
9. Manufacturer Repo		- 8. Adverse E	vent Term/s	<u> </u>	-11			
2951238-2015-0				•				
This section acrit	n anh te		he Decret	d. 19			d Liberan Dandara	OUD Statements
The public reporting burg minutes per response. In	den for this	collection of Inform	nation has be	rk Reduction Act of 1995. Sen estimated to average 6	e Foodan	nent of Health an Ind Drug Administ f Chief Informatic	nd Human Services Iration on Officer	OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of

minutes per response, including the time for reviewing instructions, searching existing data sources, galibaring and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Papervork Reduction Act (PRA) Staff PRAStaff@ida.hhs.gov PRAStaff@ida.hhs.gov PRAStaff@ida.hhs.gov Prease DO NOT RETURN this form to the above PRA Staff email address.

Charite-Universitatsmedizin Berlin, Germany



Your Vision, Our Future

Date: April 25, 2013 Report Type: Manufacturer Report 8010047-2013-00092

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event any further correspondence may be directed to my office.

Sincerely,



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Form Approved: OMB No. 09 10-029 1, Expires 12/31/11 See OMB statement on reverse.

U.S. Department of Food and Drug Add	of Health and Huma ministration	an Services	importer	rs, distrib	utor	er-facilities, s and manufacturers	Mfr Report # 8	010047-			ment on reverse
MEDWATCH	4		101			DRY reporting		4pont #			
FORM FDA 3500	DA (1/09)			Pag	e10	of 15					FDA Use Only
A. PATIENT INF						C. SUSPECT PROD	OUCT(S)				
1. Patient Identifier Unk	of Event:		3. Sex	4. Weight		1. Name (Give labeled stre	ength & mfr/iabeler)				
	or		Female		lbs	#1 N/A					
In confidence	Date of Birth:	Unk	Male	or Unk j		#2 N/A					
	ENT OR PRODU	CT PROBLE		<u></u>	kgs	2. Dose, Frequency & Ro	ute Used	3. Therap	y Dates (/	lí unknown,	give duration)
	_					#1 N/A		#1	(or best e	stimate)	
1. Adverse Event		duct Problem (e	.g., defects/malf	unctions)		#2 N/A					
(Check all that appl)						4. Diagnosis for Use (India	cetion)	#2	5 Event	Abated Afte	
Death:		Disability o	r Permanent Da	mage		#1 N/A	Callony	1		ed or Dose	
Life-threatenin	(mm/dd/yyyy) S	Congenitat	Anomaly/Birth D	Defect					#1 🗌 Y	es 🛄 No	Dcesn'i Apply
Hospitalization	- initial or prolonged	↓ Other Series	ous (Important M	ledical Ever	nts)	#2 N/A			#2 🗍 Y		Doesn'
Required Inter	vention to Prevent Permi	anent Impairmen	/Damage (Devic	es)		6. Lot #	7. Exp. Date				
3. Date of Event (mm	/dd/yyyy)	4. Date of This	Report (mm/dd	(/yyyy)	-	#1N/A	#1 N/A			Reappeared oduction?	After
. t	Jnk		3/27/2013			#2N/A	#2 N/A		#1 🗌 Y	es 🛄 No	Doesn'i
5. Describe Event or						9. NDC# or Unique ID	•				Apply     Doesn'i
	evice was retur r repair purpos					10. Concomitant Medical			#2 📋 Y		L Apply
ODE received to were treated w infection. Acc Z the same bacte	subject device the information with the subjec cording to info eria was not de was no additio	that some t device g mation fr tected from	patients ot a Klebs om the fac m the subj	which iella ility,		N/A D. SUSPECT MEDIO	CAL DEVICE				
NY NY						1. Brand Name					
8							XERA II DUOD		OSCOPE	C	
USE					1	2. Common Device Name	DUODENOENDOS	COPE			
TYPE OR (						3. Manufacturer Name, Ci OLYMPUS MEDICAL SYS 2951 Ishikawa-cho M	STEMS CORPORAT		192-850	)7 Japan	
7						4. Model #	Lot #			5. Operato	r of Device
						TJF-Q180V	N/A			🖌 Health	n Professional
AS						Catalog # N/A	Expiration	n Date (mm	dd/yyyy)	Lay U	ser/Patient
PLEASE						Serial #	Other #			Other	:
<u> </u>						2000700	N/A				
						6. If implanted, Give Date	(mm/dd/yyyy)	7. If Expla	nted, Giv	e Date (mm	/dd/yyyy)
/ ¹ 6. Relevant Tests/Lat	poratory Data, Includin	g Dates				8. Is this a Single-use Dev Yes Mo 9. If Yes to Item No. 8, En					nt?
						o, ii res to ttem No. o, En	ter name and Ado	ress of Rep	rocessor		
						10. Device Available for E	valuation? (Do not	send to FD	A)		
						🗌 Yes 🗸 No	Returned to M		<i>,</i>		
										(mm/dd/y	
7. Other Relevant His race, pregnancy, sm Un k	tory, including Preexis toking and alcohol use, i	sting Medical Co hepatic/renal dys	nditlons (e.g., a function, elc.)	flergies,	-	11. Concomitant Medical N/A	Products and The	apy Dates	(Exclude )	Ireatment of	event)
						E. INITIAL REPORT	ER			_	
						1. Name and Address	Phone	#			
						Charite-Universit Campus Virchow-K					
						Universitat zu Be Augustenburger P					
						13353 Berlin Ger					
Submission of a re personnel, user fa caused or contribution	eport does not con cility, importer, dis uted to the event.	nstitute an ad stributor, man	mission that nufacturer or	medical product	_	2. Health Professional?	3. Occupation	_	R	Report to FD	ter Also Sent DA

ME	DWA	TCH
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	A (1/09) (conti	Y/IMPORTER (De	vices Oplu)	of 15 H. DEVICE MANUFACTURERS ONLY	
Check One	JSER FACILIT	2. UF/Importer Rep		1. Type of Reportable Event	2. If Follow-up, What Type?
User Facility	Importer orter Name/Addres	55		Death     Serious Injury     Malfunction	Correction Additional Information Response to FDA Request Days for Function
				Other: Potential Infection     S. Device Evaluated by Manufacturer?     Not Returned to Manufacturer	Device Evaluation     4. Device Manufacture Date     (mm/yyyy)     August/2010
Contact Person		5. Phone Nur	nber	Yes Evaluation Summary Attached	5. Labeled for Single Use?
Date User Facility o Importer Became Aware of Event (mn	n/dd/yyyy)	Rial	. Date of This Report (mm/dd/yyyy)	6. Evaluation Codes (Refer to coding manual)	Yes 🖓 No
Approximate Age of Device		m Codes (Refer to coding	n menual)	Method	
		35 -		Results	
1. Report Sent to FD	Code	ocation Where Event O		7. If Remedial Action Initiated, Check Type	8. Usage of Device
Yes Mo (mm/do 3. Report Sent to Ma	d/yyyy) inufacturer? d/yyyyy)	Hospital Home Nursing Home Outpatient Treatment Facility	Outpatient     Diagnostic Facility     Ambulatory     Surgical Facility	Recall Notification Repair Inspection Replace Patient Monitoring Relabeling Modification/ Adjustment Other: 10. Additional Manufacturer Narrative Since the subject device had all repaired, OLYMPUS MEDICAL SYSTI evaluate it. Thus, OMSC cannot	MS CORP. (OMSC) could not
192~8507, Ja	ame/Address (and CAL SYSTEMS ra-cho, Hach: apan	CORP. Loji-shi, Tokyo	2. Phone Number 3. Report Source (Check eil that apply) Foreign Study Literature Consumer Health Professional V User Facility	the cause of this event. However, as a possible cause of this phy infected from other than the en- such as environmental factor in the same bacteria was not detend device. This report is being submitted report in an abundance of caut	er, it can be considered enomenon that patients idoscope and procedure in the facility, because oted from the subject as a medical device
4. Date Received by Manufacturer (mm 3/28/2 6. If IND, Give Proto	1/dd/yyyy) (A 2013	NDA # IND # STN #	Company Representative		
🔲 10-day 🗹 Ini	oly} -day P sriodic p tial c	Adverse Event Term(s)			
8010047-2013- The public reporting b minutes per response	urden for this collec	tion of information has be	en estimated to average 66	Department of Health and Human Services Food and Drug Administration	OMB Statement: "An agency may not conduct or spon and a person is not required to respo to, a collection of information unless i



Your Vision, Our Future

Date: July 5, 2013 Report Type: Manufacturer Report 8010047-2013-00092

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Dear MDR Coordinator,

Enclosed is a supplemental report for a previously reported 30-Day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,

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Form Approved: OMB No. 09 10-029 1, Expires 12/31/11 See OMB statement on reverse.

Mir Report # 8010047-2013-00092

U.S.	Department	of Health and	Human	Services
Food	and Drug A	dministration		

### M

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

	_	importers, distributor for MANDATC		UF/Importer Re	port #	. <u>.</u>
FORM FDA 350	-	Page 1	of 15			EDA It
A. PATIENT INF			C. SUSPECT PRO			FDA Use Onl
1. Patient Identifier		3. Sex 4. Weight	1. Name (Give labeled str			
	of Event:		#1 N/A			
	or Date		#2 N/A			
in confidence	of Birth:	Male kgs	2. Dose, Frequency & Ro	oute Used	3. Therapy Dates	(If unknown, give duration)
B. ADVERSE EV	VENT OR PRODUCT PROBL	.EM	#1 N/A		from/to (or best e #1	estimate)
1. 🗌 Adverse Even	t and/or 🗌 Product Problem	n (e.g., defects/malfunctions)				
2. Outcomes Attribut (Check all that appl			#2 N / A 4. Diagnosis for Use (Ind	lication	#2	Abated After Use
Death:	Disabili	ty or Permanent Damage	4. Diagnosis for Use (ind #1 N/A	wallony		ed or Dose Reduced?
Life-threatenin	g Conger	nital Anomaly/Birth Defect			#1 🗖 `	Yes 🗌 No 🗌 Doesr Apply
	• • •	Serious (Important Medical Events)	#2 N/A	7 Evo Data		Yes No Does
Required Inter	vention to Prevent Permanent Impairm	nent/Damage (Devices)	6. Lot# #1N/A	7. Exp. Date #1 №/A		Reappeared After
3. Date of Event (mr	n/dd/yyyy) 4. Date of T	his Report (mm/dd/yyyy)		·	Reint	roduction?
			#2N/A	#2 N/A	· [#1 []]`	Yes No Doesr Apply
'S Describe Event or his is a sup	Problem plemental report for Mf	r Report #	9. NDC# or Unique ID		#2	Yes No Doesi
8010047-2013-	00092 to provide additi	onal information	10. Concomitant Medica	Products and The	rapy Dates (Exclude	
	report from the user fa ent Authority in German		N/A			
A patient who	had been diagnosed wit	h Klebsiella				
	s examined on February evice was used to carry					
1 "	evice was used to carry tion on twenty-six pati	-				
	and March 11th before i epair. Subsequently, K.		D. SUSPECT MED 1. Brand Name	ICAL DEVICE		
	epair. Subsequently, K. ese patients. Two of th					
1	LYMPUS MEDICAL SYSTEMS		2. Common Device Nam	e		
informed the	cause of the patient de	atn.	3. Manufacturer Name,	City and State		ž
			4. Model #	Lot #		5. Operator of Device
						Health Profession
			Catalog #	Expiratio	n Date (mm/dd/yyyy	Lay User/Patient
			Serial #	Other #		Other:
1						
			6. If Implanted, Give Da	te (mm/dd/yyyy)	7. If Explanted, G	iive Date (mm/dd/yyyy)
6. Relevant Tests/La	boratory Data, Including Dates		8. Is this a Single-use D	evice that was Rep	rocessed and Reus	ed on a Patient?
1			Yes No			
			9. If Yes to Item No. 8, E	Inter Name and Add	dress of Reprocess	or
			10. Device Available for	Evaluation? (Do no	of send to FDA)	
			Yes No	Returned to M	Manufacturer on:	(mm/dd/yyyy)
			11. Concomitant Medic	al Products and The	erapy Dates (Exclud	
7. Other Relevant H	istory, Including Preexisting Medica	Conditions (e.g., allergies,				
race, pregnancy, s	moking and alcohol use, hepatic/renal	oysiancion, etc.)	1			
			E. INITIAL REPOR	RTER		
			1. Name and Address	Phon	e #	
1				L		
			O Haalih Darfaari	2 October		. Initial Reporter Also S
personnel, user t	report does not constitute ar facility, importer, distributor,		2. Health Professional	- S. Occupation		Report to FDA
caused or contri	buted to the event.	•				🖲 Yes 🗌 No 🔄 l

.

	USER FACIL	ITY/IMPORTER (De	vices Only)	H. DEVICE MANUFAC	TURERS ONLY	
Check One		2. UF/Importer Re	eport Number	1. Type of Reportable Event		2. If Follow-up, What Type?
User Facility	Importer			Death		
User Facility or Imp	porter Name/Add	ress		Serious Injury		Additional Information
				Malfunction		Response to FDA Reque     Device Evaluation
				Other:		
				3. Device Evaluated by Manu		<ol> <li>Device Manufacture Date (mm/yyyy)</li> </ol>
		C. Dhara Nu		Not Returned to Manu		
Contact Person		5. Phone Nu	mper	Yes Evaluation	Summary Attached	5. Labeled for Single Use?
Date User Facility	or 7. T	ype of Report	8. Date of This Report	provide code:	plant why holy of	Yes No
Importer Became Aware of Event (mi		Initial	(mm/dd/yyyy)			
		Follow-up #		6. Evaluation Codes (Refer to	coding manual)	
Approximate	10. Event Prob	lem Codes (Refer to codin	a manual)	Method	]_	
Age of Device	Patient	[				
	Code			Results		
	Device Code			Conclusions	-	<b>-</b>
. Report Sent to FC		. Location Where Event C	Dccurred	7. If Remedial Action Initiate	d, Check Type	8. Usage of Device
Yes		Hospital	Outpatient	Recali N	otification	Initial Use of Device
	ld/yyyy)	Home	└── Diagnostic Facility ┌── Ambulatory		spection	Reuse
. Report Sent to Ma	anufacturer?	Nursing Home	Surgical Facility		atient Monitoring	Unknown
Yes		Outpatient Treatmen Facility	t		fodification/ djustment	9. If action reported to FDA under 21 USC 360i(f), list correction/
	td/yyyy)	Other:		Other:	ujusunen.	removal reporting number:
. Manufacturer Nai			(Specify)			
				EUROPA disassemble with personnels fr samples from each	equest from t d the subject om the user f part dismantl	and/or 11. Corrected Da the user facility, OLYMM device in conjunction facility. They took eighted from the subject
G: ALL MANUF . Contact Office - N for Devices)		nd Manufacturing Site	2. Phone Number 3. Report Source (Check all that apply) Foreign	According to the r EUROPA disassemble with personnels fr samples from each device for culture facility brought t test. Subsequently were tested negati Based on the resul SYSTEMS CORP. thin	equest from t d the subject om the user f part dismantl test. The pe them back and d, all samples .ve. .t of the cult bks that this	he user facility, OLYM device in conjunction facility. They took eigh
. Contact Office - N		nd Manufacturing Site	3. Report Source (Check all that apply)	According to the r EUROPA disassemble with personnels fr samples from each device for culture facility brought t test. Subsequently were tested negati Based on the resul SYSTEMS CORP. thin	equest from t d the subject om the user f part dismantl test. The pe them back and d, all samples .ve. .t of the cult bks that this	the user facility, OLYMI to device in conjunction facility. They took eighted from the subject ersonnels from the user performed the culture to collected from the part ture test, OLYMPUS MEDIField event was most likely
Contact Office - N		nd Manufacturing Site	3. Report Source (Check all that apply) Foreign Study Literature	According to the r EUROPA disassemble with personnels fr samples from each device for culture facility brought t test. Subsequently were tested negati Based on the resul SYSTEMS CORP. thin	equest from t d the subject om the user f part dismantl test. The pe them back and d, all samples .ve. .t of the cult bks that this	the user facility, OLYMI to device in conjunction facility. They took eighted from the subject ersonnels from the user performed the culture to collected from the part ture test, OLYMPUS MEDIField event was most likely
Contact Office - N		nd Manufacturing Site	3. Report Source (Check all that apply) Foreign Sludy Literature Consumer	According to the r EUROPA disassemble with personnels fr samples from each device for culture facility brought t test. Subsequently were tested negati Based on the resul SYSTEMS CORP. thin	equest from t d the subject om the user f part dismantl test. The pe them back and d, all samples .ve. .t of the cult bks that this	the user facility, OLYM: term device in conjunction facility. They took eighted from the subject ersonnels from the user performed the culture s collected from the pa ture test, OLYMPUS MEDI event was most likely
Contact Office - N for Devices)	ame/Address (ar		3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional	According to the r EUROPA disassemble with personnels fr samples from each device for culture facility brought t test. Subsequently were tested negati Based on the resul SYSTEMS CORP. thin	equest from t d the subject om the user f part dismantl test. The pe them back and d, all samples .ve. .t of the cult bks that this	the user facility, OLYM: term device in conjunction facility. They took eighted from the subject ersonnels from the user performed the culture s collected from the pa ture test, OLYMPUS MEDI event was most likely
Contact Office - N for Devices)	ame/Address (ar	5. (A)NDA #	3. Report Source (Check all that apply) Foreign Sludy Literature Consumer Health Professional User Facility Company Representative	According to the r EUROPA disassemble with personnels fr samples from each device for culture facility brought t test. Subsequently were tested negati Based on the resul SYSTEMS CORP. thin	equest from t d the subject om the user f part dismantl test. The pe them back and d, all samples .ve. .t of the cult bks that this	the user facility, OLYM: term device in conjunction facility. They took eighted from the subject ersonnels from the user performed the culture s collected from the pa ture test, OLYMPUS MEDI event was most likely
Contact Office - N for Devices) Date Received by Manufacturer (mn	ame/Address (ar , n/dd/yyyy)	5.	3. Report Source (Check all that apply) Foreign Sludy Literature Consumer Health Professional Vuser Facility Company	According to the r EUROPA disassemble with personnels fr samples from each device for culture facility brought t test. Subsequently were tested negati Based on the resul SYSTEMS CORP. thin	equest from t d the subject om the user f part dismantl test. The pe them back and d, all samples .ve. .t of the cult bks that this	the user facility, OLYMI to device in conjunction facility. They took eighted from the subject ersonnels from the user performed the culture to collected from the part ture test, OLYMPUS MEDIField event was most likely
Contact Office - N for Devices) . Date Received by Manufacturer (mn . If IND, Give Proto . Type of Report	n/dd/yyyy) n/dd/yyyy) col #	5. (A)NDA # IND # STN # PMA/	3. Report Source (Check all that apply) Foreign Sludy Literature Consumer Health Professional User Facility Company Representative Distributor	According to the r EUROPA disassemble with personnels fr samples from each device for culture facility brought t test. Subsequently were tested negati Based on the resul SYSTEMS CORP. thin	equest from t d the subject om the user f part dismantl test. The pe them back and d, all samples .ve. .t of the cult bks that this	the user facility, OLYMI to device in conjunction facility. They took eighted from the subject ersonnels from the user performed the culture to collected from the part ture test, OLYMPUS MEDIField event was most likely
Contact Office - N for Devices)  Date Received by Manufacturer (mn  Manufacturer (mn  If IND, Give Proto  Type of Report (Check all that app	n/dd/yyyy) n/dd/yyyy) col #	5. (A)NDA # IND # STN # PMA/ 510(k) # Combination	3. Report Source (Check all that apply) Foreign Sludy Literature Consumer Health Professional User Facility Company Representative Distributor	According to the r EUROPA disassemble with personnels fr samples from each device for culture facility brought t test. Subsequently were tested negati Based on the resul SYSTEMS CORP. thin	equest from t d the subject om the user f part dismantl test. The pe them back and d, all samples .ve. .t of the cult bks that this	the user facility, OLYMI to device in conjunction facility. They took eighted from the subject ersonnels from the user performed the culture to collected from the part true test, OLYMPUS MEDI( event was most likely
Contact Office - N for Devices) . Date Received by Manufacturer (ma b. If IND, Give Proto . Type of Report (Check all that app . 5-day	n/dd/yyyy) n/dd/yyyy) col # -day	5. (A)NDA # IND # STN # PMA/ 510(k) # Combination ProductYes	3. Report Source (Check all that apply) Foreign Sludy Literature Consumer Health Professional User Facility Company Representative Distributor	According to the r EUROPA disassemble with personnels fr samples from each device for culture facility brought t test. Subsequently were tested negati Based on the resul SYSTEMS CORP. thin	equest from t d the subject om the user f part dismantl test. The pe them back and d, all samples .ve. .t of the cult bks that this	the user facility, OLYMI to device in conjunction facility. They took eighted from the subject ersonnels from the user performed the culture to collected from the part true test, OLYMPUS MEDI( event was most likely
Contact Office - N for Devices) Date Received by Manufacturer (mn . If IND, Give Proto . Type of Report (Check all that app	n/dd/yyyy) n/dd/yyyy) col #	5. (A)NDA #	3. Report Source (Check all that apply) Foreign Sludy Literature Consumer Health Professional User Facility Company Representative Distributor	According to the r EUROPA disassemble with personnels fr samples from each device for culture facility brought t test. Subsequently were tested negati Based on the resul SYSTEMS CORP. thin	equest from t d the subject om the user f part dismantl test. The pe them back and d, all samples .ve. .t of the cult bks that this	the user facility, OLYM: term device in conjunction facility. They took eighted from the subject ersonnels from the user performed the culture s collected from the pa ture test, OLYMPUS MEDI event was most likely
Contact Office - N for Devices)  Date Received by Manufacturer (mm Anufacturer (mm B. If IND, Give Proto Check all that app 5-day 30 7.7day Pe 10-day Ini	n/dd/yyyy) n/dd/yyyy) col # -/y) i-day ariodic	5. (A)NDA # IND # STN # PMA/ 510(k) # Combination ProductYes	3. Report Source (Check all that apply) Foreign Sludy Literature Consumer Health Professional User Facility Company Representative Distributor	According to the r EUROPA disassemble with personnels fr samples from each device for culture facility brought t test. Subsequently were tested negati Based on the resul SYSTEMS CORP. thin	equest from t d the subject om the user f part dismantl test. The pe them back and d, all samples .ve. .t of the cult bks that this	the user facility, OLYMI to device in conjunction facility. They took eighted from the subject ersonnels from the user performed the culture to collected from the part ture test, OLYMPUS MEDIField event was most likely
Contact Office - N for Devices)  Date Received by Manufacturer (mm Anufacturer (mm Anufacture	n/dd/yyyy) n/dd/yyyy) col # -day sriodic itial sllow-up # <u>1</u>	5. (A)NDA #	3. Report Source (Check all that apply) Foreign Sludy Literature Consumer Health Professional Viser Facility Company Representative Distributor Other:	According to the r EUROPA disassemble with personnels fr samples from each device for culture facility brought t test. Subsequently were tested negati Based on the resul SYSTEMS CORP. thin	equest from t d the subject om the user f part dismantl test. The pe them back and d, all samples .ve. .t of the cult bks that this	the user facility, OLYMI to device in conjunction facility. They took eighted from the subject ersonnels from the user performed the culture to collected from the part ture test, OLYMPUS MEDIField event was most likely
Contact Office - N for Devices)  Date Received by Manufacturer (mn Anufacturer (mn Anufacturer (mn Check all that app Check all that app 5-day 30 7-day Pe 10-day 110-day 110-	n/dd/yyyy) n/dd/yyyy) col # bly) -day ariodic itial silow-up # <u>1</u> port Number	5. {A}NDA # IND # STN # PMA/ 510(k) # Combination Product Yes Pre-1938 Yes OTC Product Yes	3. Report Source (Check all that apply) Foreign Sludy Literature Consumer Health Professional Viser Facility Company Representative Distributor Other:	According to the r EUROPA disassemble with personnels fr samples from each device for culture facility brought t test. Subsequently were tested negati Based on the resul SYSTEMS CORP. thin	equest from t d the subject om the user f part dismantl test. The pe them back and d, all samples .ve. .t of the cult bks that this	the user facility, OLYMI to device in conjunction facility. They took eighted from the subject ersonnels from the user performed the culture to collected from the part true test, OLYMPUS MEDI( event was most likely
Contact Office - N for Devices) Date Received by Manufacturer (ma h If IND, Give Proto Check all that app 5-day 30 7-day 94 10-day 16 15-day 75 6. Manufacturer Ref	n/dd/yyyy) n/dd/yyyy) col # bly) -day ariodic itial silow-up # <u>1</u> port Number	5. {A}NDA # IND # STN # PMA/ 510(k) # Combination Product Yes Pre-1938 Yes OTC Product Yes	3. Report Source (Check all that apply) Foreign Sludy Literature Consumer Health Professional Viser Facility Company Representative Distributor Other:	According to the r EUROPA disassemble with personnels fr samples from each device for culture facility brought t test. Subsequently were tested negati Based on the resul SYSTEMS CORP. thin	equest from t d the subject om the user f part dismantl test. The pe them back and d, all samples .ve. .t of the cult bks that this	the user facility, OLYMI to device in conjunction facility. They took eighted from the subject ersonnels from the user performed the culture to collected from the part ture test, OLYMPUS MEDIField event was most likely

Rockville, MD 20857 Please DO NOT RETURN this form to this address.

# **Clinique De Bercy Charenton-le-Pont, France**

8-12-0045:

FR

OCA_0001713



Your Vision, Our Future

Date: December 20, 2012 Report Type: Manufacturer Report 8010047-2012-000452

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event any further correspondence may be directed to my office.

Sincerely,

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Mfr Report # 8010047-2012-00452

UF/Importer Report #

U.S. Department of Health and Human Services Food and Drug Administration

## MEDWATCH

For use by user-facilities,
importers, distributors and manufacturers
for MANDATORY reporting
For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

MEDWATCH						
FORM FDA 3500A (1/09)	Page 1 of	15			,	FDA Use Only
A. PATIENT INFORMATION		C. SUSPECT PRODU	CT(S)			
1. Patient Identifier 2. Age at Time	3. Sex 4. Weight 1	1. Name (Give labeled streng	th & mfr/labeler)			
of Event:	Female ibs	#1				
Date	or	#2				
in confidence of Birth:	Male kgs	2. Dose, Frequency & Route	Used 3	Therapy Dates (	funknown a	ive duration1
B. ADVERSE EVENT OR PRODUCT PROBL	EM			from/to (or best es	stimate)	10 0010001
1. V Adverse Event and/or Product Problem	(e.g., defects/malfunctions)	#1		#1		
2. Outcomes Attributed to Adverse Event		#2	1	#2		
(Check all that apply)		4. Diagnosis for Use (Indical	ion)		Abated After	
Death: Disability	y or Permanent Damage	#1			ed or Dose R	
	ital Anomaly/Birth Defect			#1 └_ Y	es 🗌 No	Doesn't Apply
Hospitalization - initial or prolonged Other Se	erious (Important Medical Events)	#2			es 🗌 No	Doesn't
Required Intervention to Prevent Permanent Impairme		6. Lot #	. Exp. Date			Apply
	is Report (mm/dd/yyyy)	#1	#1		Reappeared oduction?	After
10/08/2012		#2	#2	_	es 🗍 No	Doesn't
5. Describe Event or Problem		9. NDC# or Unique ID	•••			- Apply
Ty user facility reported to identif				#2 🗋 Y	es 🔲 No	Doesn't Apply
setions of 3 patients that underwe		10. Concomitant Medical Pr	oducts and Therapy	v Dates (Exclude t	realment of a	
facility and tested positive for Esch	nerichia coli. There	N/A		,		, , , , , , , , , , , , , , , , , , ,
was no report of infections or other	patient harm.					
4						
3						
5	i I	D. SUSPECT MEDIC/	AL DEVICE			
WAR WORTH TOO	í F	1. Brand Name	ERA II DUODEN	JOUTDEOSCOPE		
3			KA II DOODEN	NOVIDEOSCOPE	, 	
3		2. Common Device Name	UODENOENDOSC	COPE		
2		3. Manufacturer Name, City	and State			
		OLYMPUS MEDICAL SYST 2951 Ishikawa-cho Ha			Japan	
1	1 5	4. Model #	Lot #		5. Operator	of Device
-		TJF-Q180V			Z Health	Professional
10001		Catalog #	Expiration D	ate (mm/dd/yyyy)	-	er/Patient
3		Serial #	Other #	,	Other:	
	1 4	2101357		KE STATE		
	i 1	<ol><li>If Implanted, Give Date (r)</li></ol>		. If Explanted, Giv	e Date (mm/	аалуууу)
d vant Tests/Laboratory Data, Including Dates		8. Is this a Single-use Devic	e that was Reproce	essed and Reuse	d on a Patier	
l ·		Yes V No				
	7	9. If Yes to Item No. 8, Ente	r Name and Addres	s of Reprocessor		
}						
		10. Device Available for Eva	luation? (Do not se	end to FDA)		
		🗌 Yes 🚺 No 🚺	Returned to Manu	ufacturer on:		
				Batas (Batas	(mm/dd/y)	
		11. Concomitant Medical Pr	oducts and Therap	by Dates (Exclude	treatment of	event)
<ol><li>Other Relevant History, Including Preexisting Medical race, pregnancy, smoking and alcohol use, hepatic/renal of</li></ol>	Conditions (e.g., allergies,					
teed, programy, enoung and address add, repationera	,					
		E. INITIAL REPORTE	R			
		1. Name and Address	Phone_#			
		Clinique De Bercy				
		Charention Le Poir	nt, 94, Franc	ce ·		
Submission of a report does not constitute an a	admission that medical	2. Health Professional? 3.	Occupation	4	nitial Report	ter Also Sent
personnel, user facility, importer, distributor, m	nanufacturer or product	1	•	1	Report to FD	A
caused or contributed to the event.	• • • • • • •	Yes No Ot	ner Healthcare Prof	lessional	Yes 💽	No 🗍 Unk,

OCA_0001714

## MEDWATCH

Page 2 ^r of 15	

FDA USE ONLY

FORM FDA 3500	A (1/09)	(continued)		Page 2	2 [.] of 15				
F. FOR USE BY	USER FA	CILITY/IMPO	RTER (D	evices Only)	H. DEVICE MANUF	ACTURERS ONLY			
1. Check One			F/Importer R	aport Number	1. Type of Reportable Eve	1. Type of Reportable Event			
User Facility	Impo				Death				
3. User Facility or Importer Name/Address			Serious Injury		Additional Information				
			Malfunction		Response to FDA Request				
				Other: Potenti	al Infection	Device Evaluation			
					3. Device Evaluated by M	anufacturer?	<ol> <li>Device Manufacture Date (mm/yyyy)</li> </ol>		
					✓ Not Returned to M		01/2011		
4. Contact Person			5. Phone Nu	mber					
6. Date User Facility of		7. Type of Repo	rt I	8. Date of This Report	No (Attach page to explain why not) or provide code:		5. Labeled for Single Use?		
Importer Became Aware of Event (mm	I	Initial		(mm/dd/yyyy)			🗌 Yes 🗹 No		
					6. Evaluation Codes (Refe	er to coding manual)			
9. Approximate	10 Event F	Follow-up # Problem Codes		a mapual)	Method				
Age of Device	_	-Toblem Codes			incurve (				
	Patient Code	2199	-		Results				
	Device	1091	-	<b>_</b>	Conclusions	67 - 92	]_[]		
11 rt Sent to FDA	Code	12. Location V	Vhere Event C	Decurred	7. If Remedial Action Initi		8. Usage of Device		
Yes	- *	Hospit		Outpatient	1	Notification	Initial Use of Device		
(mm/dd)	/уууу)	Home		Diagnostic Facility	Repair	Inspection	Reuse		
13. Report Sent to Man	ufacturer?	Nursin	g Home	Ambulatory Surgical Facility		Patient Monitoring	Unknown		
T Yes		Outpat Facility	ient Treatmen '	t	Relabeling	10000000000	9. If action reported to FDA under 21 USC 360i(f), list correction/		
No (mm/dd)	(YYYY)	Other:			Other:	Adjustment	removal reporting number:		
14. Manufacturer Name	•14 dd ====			(Specify)					
14. manufacturer Name	erAduress								
					10. Additional Manufa		and/or 11. Corrected Data er facility to obtain		
						•	g this report, and was		
							en cultured, but was		
G. ALL MANUFA	CTHDED	2			negative for gro The subject devi		lity. rned to Olympus for		
1. Contact Office - Nam			ırina Site	2. Phone Number	evaluation, and	will be sent to	an independent		
for Devices)			9				robiological testing. At se of the reported		
				3. Report Source	phenomenon canno	t be determined,	, however insufficient		
OLYMPUS MEDIC 2951 Ishikawa			. mahua	(Check all that apply) ✓ Foreign		-	cannot be ruled out as		
1,02-8507, Jap		achioji-sh	1, токуо	Study	contributory factors. If significant additional information is received, a				
				Literature	supplemental report will follow.				
,				Consumer	This report is b	eing submitted a	as a Medical Device		
				Health Professional	Report in an abu				
4. Date Received by		5.		User Facility	Cross-reference	Mfr. Benort# 80	10047-2012-00453, and		
Manufacturer (mm/d		(A)NDA #		Company Representative	8010047-2012-004				
6. If IND, Give Protoco		IND#		Distributor					
6. IT IND, GIVE PIOLOCO	1 #	STN #		Other:					
7. Type of Report		PMA/							
(Check all that apply)	ŧ	510(k) #							
5-day 🗹 30-da		Combination Product	Yes Yes						
Perio		Pre-1938	Yes						
	w-up #	OTC Product	Yes						
9. Manufacturer Repor		8. Adverse E	vent Term(s)	I					
8010047-2012-0									
The public reporting burg	den for this o	collection of inform	nation has been	en estimated to average 66	Department of Health and H	uman Services	OMB Statement:		
minutes per response, in sources, gathering and n	icluding the i	time for reviewing	instructions,	searching existing data	Food and Drug Administrati	on	"An agency may not conduct or sponsor, and a person is not required to respond		
collection of information. this collection of informat	Send comm	nents regarding ti	nis burden esti	mate or any other aspect of	5600 Fishers Lane Rockville, MD 20857		An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."		

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Form Approved: OMB No. 09 10-029 1, Expires 12/31/51 See OMB statement on reverse.

U.S. Department Food and Drug Ad	of Health and Hum Iministration	nan Services	For use by u		Mfr Report # 8	010047-2013	-00595
MEDWATC			for MANDAT	rs and manufacturers ORY reporting	UF/importer Re	sport #	
FORM FDA 350	00A (1/09)		Page 1	of 15			FDA Use Only
A. PATIENT IN	FORMATION			C. SUSPECT PRO	DUCT(S)		FDA USE Only
1. Patient Identifier	2. Age at Time		3. Sex 4. Weight	1. Name (Give labeled str			
Unk	of Event: Unk		Esmale Unk lbs	#1 N/A			
	or		Female On K lbs				
In confidence	Date of Birth:	Unk	Male Unk kgs	#2 N/A			
B. ADVERSE E	VENT OR PRODU	CT PROBLE	M	2. Dose, Frequency & Ro	oute Used	frcm/lo (or bes	s (if unknown, give duration) st estimate)
1. Adverse Eve	nt and/or Pro	oduct Problem /	e.g., defects/malfunctions)	#1 N/A		#1	
	ited to Adverse Event	our content (	.g., autociamananosonaj	#2 N/A		#2	
(Check all that app				4. Diagnosis for Use (Inc	dication)	5. Eve	nt Abated After Use
Death:	(mm/dd/yyyy)	_ Disability	or Permanent Damage	#1 N/A			pped or Dose Reduced?
Life-threateni		Congenita	Anomaly/Birth Defect	#2 N/A		#1 L_	] Yes 🗌 No 🔂 Doesn't Apply
Hospitalizatio	n - initial or prolonged	7 Other Ser	ious (Important Medical Events)	6. Lot #	7 Evo Data	#2	Yes No Doesn't
Required Inte	rvention to Prevent Perm	nanent Impairmer	VDamage (Devices)		7. Exp. Date #1 N/A		nt Reappeared After
3. Date of Event (m	m/dd/yyyy)	4. Date of This	Report (mm/dd/yyyy)	#1N/A	-   #1 N/A		ntroduction?
( 11/	08/2013		11/21/2013	#2N/A	#2 N/A	#1	] Yes 🗋 No 🗌 Doesn't Apply
5. Describe Event o	r Problem			9. NDC# or Unique ID			Yes No Doesn'i
Olympus Media	al Systems COR	P. (OMSC) »	as informed that	10. Concomitant Medica			
(ERCP) using Pseudomonas v facility said instrument ch		vice, Enter rom two pat eria were d suction cha	obacteries and ients. The user letected from the nnel of the	N/A			
Unknown.			-	D. SUSPECT MED	ICAL DEVICE		
ILA				1. Brand Name EVIS 1	EXERA II DUOI	DENOVIDEOSCO	PE
				2. Common Device Nam	e		
S						SCOPE	
EOR				<ol> <li>Manufacturer Name, C OLYMPUS MEDICAL SY 2951 Ishikawa-cho</li> </ol>	STEMS CORPORAT		3507 Japan
4			Í	4. Model #	Lot #		5. Operator of Device
				TJF-Q180V	N/A		Health Professional
ASI .				Catalog #	Expiratio	n Date (mm/dd/yyy	29 Lay User/Patient
E CE				Serial #	Other #		Other:
R				2101336	N/A		
( '				6. If Implanted, Give Dat	e (mm/dd/yyyy)	7. If Explanted,	Give Date (mm/dd/yyyy)
6. Relevant Tests/La Unk	aboratory Data, Includir	ng Dates		8. Is this a Single-use Do	·		
				9. If Yes to liem No. 8, E	nter Name and Add	iress of Reproces:	sor
				10. Device Available for	Evaluation? (Do no	( send to FDA)	
				🗌 Yes 🔽 No	Returned to N		
							(mm/dd/yyyy)
				11. Concomitant Medica N/A	Products and The	rapy Dates (Exclu	de treatment of event)
	istory, Including Preexi moking and alcohol use,	isting Medical Co hepalic/renal dys	onditions (e.g., allergies, function, etc.)				
Unk							
				E. INITIAL REPOR		4	
				1. Name and Address	Phone		
				Clinique de Berc 9 Quai de Bercy,		enton-le-Pon	t, France
personnel, user f	report does not co acility, importer, di outed to the event.	nstitute an ac stributor, ma	mission that medical nufacturer or product	2. Health Professional?	3. Occupation		4. Initial Reporter Also Sent Report to FDA

MEDWATCH	ł
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							FDA USE ONLY
MEDWATCH				<b>D</b>			
FORM FDA 3500				Page 2			
F. FOR USE BY U	ISER FA			vices Only)	H. DEVICE MANUE 1. Type of Reportable Ex	FACTURERS ONLY	2. If Follow-up, What Type?
1. Check One User Facility	🗍 Impo	1	porter Rep		Death		Correction
3. User Facility or Impo					Serious Injury		Additional Information
•					Maifunction		Response to FDA Request
					Other: Potent	ial Infection	Device Evaluation
					3. Device Evaluated by	Manufacturer?	<ol> <li>Device Manufacture Date (mm/yyyy)</li> </ol>
					Not Returned to		01/2011
4. Contact Person		5. P	hone Num	ıber		ation Summary Attached	5. Labeled for Single Use?
6. Date User Facility or		7. Type of Report	8	Date of This Report	provide code:	to explain why not) or	∏Yes √ No
Importer Became Aware of Event (mm		Initial		(mm/dd/yyyy)			
		Follow-up #			6. Evaluation Codes (Re	efer to coding manual)	
9. Approximate	10. Event	Problem Codes (Refe	r to coding	manual)	Method	-	
Age of Device	Patient				Results		
	Code	1735 -			Rosuits		
	Code	3190 -			Conclusions	67 - 92	
11. Report Sent to FDA	47	12. Location Where	Event Oc		7. If Remedial Action In	itiated, Check Type	8. Usage of Device
Yes	Kanad	Hospital		Outpatient Diagnostic Facility	Recall	Notification	Initial Use of Device
I No (mm/dd)		Home	ma	Ambulatory Surgical Facility	Repair	Inspection Patient Monitoring	Unknown
13. Report Sent to Mar	nufacturer	Outpatient		Surgical Facility	Replace	Modification/	9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:
Yes(mm/dd	(vvv)	Facility				Adjustment	removal reporting number:
N₀ (*****		Other:		(Specify)	Other:		
14. Manufacturer Nam	e/Address				10. Additional Man		and / or 11. Corrected Data
192-8507, Jag         4. Date Received by Manufacturer (mm/ 11/25/2         6. If IND, Give Protoc         7. Type of Report (Check all that appl)         5-day       30-d         7-day       Peri 10-day	CAL SYS a-cho, I pan (dd/yyyy) 2013 col # y) day iodic al low-up # ort Number	S. (and Manufacturing TEMS CORP. Hachioji-shi, (A)NDA # ND # STN # PMA/ 510(k) # Combination Product [ Pre-1938 [ OTC Product [	Tokyo Yes Yes	2. Phone Number 3. Report Source (Check all that apply)  ✓ Foreign Study Literature Consumer ✓ Health Professional ✓ User Facility Company Representative Distributor Other:	the facility. T instrument char instrument char which Olympus of instruction mar the specific cl instrument char cleaning brush suction channel However, improv	The facility brus mel, the suction inel opening with ioes not recommen- ual of the subject teaning brush for mel opening, while used for the ine- 1. Olympus Medici- refer the root of	e reprocessing practice in thed the distal end, the a channel, and the a the same cleaning brush, dd. In addition, the set device directs to use the distal end and the ch is different from the strument channel and the al Systems CORP (OMSC) ause of this event. could not be ruled out as eported event.
minutes per response,	including th I maintaining n. Send con	e time for reviewing in: g the data needed, and nments regarding this t	structions, I completin burden esti	g and reviewing the mate or any other aspect (	Office of Chief Informati 5600 Fishers Lane Rockville, MD 20857	tration	OMB Statement: "An agency may not conduct or sponso and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number." 255.



Your Vision, Our Future

Date: March 16, 2015 Report Type: Manufacturer Report (30day) #8010047-2015-00210

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,

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			Form	Approved: OMB No	, 0910-0291, Ex See OMB stater	pires; 6/30/20
U.S. Department of Health and Human Services Food and Drug Administration	For use by u		Mfr Report # 8	010047-2015	-00210	ingin on level.
	importers, distributo for MANDAT	rs and manufacturers ORY reporting	UF/Importer Re			
MEDWATCH	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		· <u>**** · · · · · ·</u>		<u>. Augustan a</u> ng a lin an ang	
FORM FDA 3500A (2/13)	Page 1	of <u>-</u>		· 4 /		FDA Use On
A. PATIENT INFORMATION 1. Patient Identifier 2. Age at Time	2 5	C. SUSPECT PROD				
of Event:	3. Sex 4. Weight	1. Name (Give labeled stree	ngth & mtrifabeler)			(, *
or	Female Ibs	#1				
In confidence of Birth:	Male kgs	#2				
B. ADVERSE EVENT OR PRODUCT PROBLEM	Ŵ	2. Dose, Frequency & Rou	ite Used	3. Therapy Dates fromito (or best	(if unknown, j estimate)	give duration
1. Adverse Event and/or Product Problem (e.	.g., defects/maifunctions)	#1		#1		
2. Outcomes Attributed to Adverse Event (Check all that apply)		#2		#2		
	r Permanent Damage	4. Diagnosis for Use (India	ation)		t Abated Afte ped or Dose	
(mm/dd/yyyy)	Anomaly/Birth Defect	#1			Yes 🗌 No	Doese Apply
	ous (Important Medical Events)	#2			Yes No	Doesr
Required Intervention to Prevent Permanent Impairment	/Damage (Devices)	6. Lot #	7. Exp. Date			
	Report (mmlddlyyyy)	I #1	#1	8. Ever Rein	t Reappeared troduction?	After
11/08/2013	11/21/2013	#2	#2	#1 🗌	Yes 🗋 No	Doesi Apply
5. Describe Event or Problem		9. NDC# or Unique ID		#2	Yes 🗍 No	Does
after endoscopic retrograde cholangiops (ERCP) using the subject device, Enterc Pseudomonas were detected from two path facility said the same bacteria were de instrument channel and the suction char subject device, too. The outcome of the	bbacteries and ients. The user etected from the nnel of the				Continue or	n page 3)
unknown.	s patrents 15	D. SUSPECT MEDIO	AL DEVICE			
		1. Brand Name EVIS EX	KERA II DUON	ENOVIDEOSCO	PE	
		2. Common Device Name		2b.	Procode	-
		DUODENOENDOSCOPE 3. Manufacturer Name, Cit	t and State			
		OLYMPUS MEDICAL SYS 2951 Ishikawa-cho H	TEMS CORPORAT		507 Japan	
		4. Model #	Lot#		5. Operato	r of Device
		TJF-Q180V Catalog #	N/A Expiration	Date (mm/dd/yyyy)	- 🖌 Health	n Profession:
		TJF-Q180V		N/A	Lay U	ser/Patient
		Serial #		ntifier (UDI) #	Other:	:
		2101336 6. If implanted, Give Date	N/A (mmiddlywyy)	7. If Explanted, G	live Date (mm	Iddhonad
	(Continue on page 3)	N/A	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	N/A	inte Date (inin	
Laboratory Data, including Dates		8. Is this a Single-use Dev	ice that was Repr	ocessed and Reus	ed on a Patie	nt?
		9. If Yes to item No. 8, Ent	er Name and Add	ress of Reprocess	or	
		10. Device Available for Ev	aluation? (Do not	send to FDA)		
			Returned to M			
					(mm/ddly	
	(Continue on page 3)	11. Concomitant Medical P	roducts and The	rapy Dates (Exclud	le treatment of	event)
<ol> <li>Other Relevant History, Including Preexisting Medical Cor race, pregnancy, smoking and alcohol use, hepaticirenal dysto</li> </ol>	unction, etc.)					
				(	Continue or	1 page 3)
		E. INITIAL REPORT 1. Name and Address	EK			
		Clinique de Bercy				
		9 Quai de Bercy,		nton-le-Pont	, France	
l		Dhana dh				
	(Continue on page 3)	Phone #	Ema	il Address		_
Submission of a report does not constitute an adm	nission that medical	2. Health Professional? 3	. Occupation	4	Initial Repor	
personnel, user facility, importer, distributor, man caused or contributed to the event.		Yes No			Report to FD	A
to the office						

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MEDW	ATCL			-		FDA USE ONLY		
		-	Page 2	of 2				
FORM FDA 3500				H. DEVICE MANUFACT		and the second second		
1. Check One	JSER FAC	2. UF/Importer R		1. Type of Reportable Event	UKEKS UNET	2. If Follow-up, What Type?		
User Facility	lmport			Death		Correction		
3. User Facility or Impo	orter Name/A	ddress		Serious Injury		Additional Information		
				Malfunction		Response to FDA Request		
						Device Evaluation		
				3. Device Evaluated by Manufa	cturer?	<ol> <li>Device Manufacture Date (mm/yyyy)</li> </ol>		
				Not Returned to Manufac				
4. Contact Person		5. Phone Nu	umber	Yes Evaluation St	ummary Attached	5. Labeled for Single Use?		
6. Date User Facility or	r 7.	Type of Report	8. Date of This Report	provide code:	an why holy of	Yes INo		
Importer Became Aware of Event (mm		Initial	(mmiddlyyyy)			-		
		Follow-up #		6. Event Problem and Evaluation	on Codes (Refer to	coding manual)		
9. Approximate		roblem Codes (Refer to codir	ng manual)	Patlent Code	1735 -	-		
Age of Device	Patient			Device	3190 -	-		
	Code			Code				
	Code			Method				
11. Report Sent to FDA	17	12. Location Where Event		Results	-			
Yes (mm/ddl	//////	Hospital	Diagnostic Facility	Conclusions	57 - 92			
		Nursing Home	Ambulatory Surgical Facility	7. If Remedial Action Initiated,		B. Usage of Device		
13. Report Sent to Mar	nuracturer r	Outpatient Treatmen				Initial Use of Device		
Yes(mm/dd	199999)	Facility			fication	Reuse		
			(Specify)		ent Monitoring	Unknown		
14. Manufacturer Nam	e/Address				dification/ ustment	<ol> <li>If action reported to FDA under 21 USC 360i(f), list correction/</li> </ol>		
				Other:		removal reporting number:		
				10. 🖌 Additional Manufacture	er Narrative	and / or 11. Corrected Data		
G. ALL MANUFA	CTURER	5		This report is being	g submitted	upon further review of		
1. Contact Office (and	Manufacturi	ing Site for Devices)	2. Phone Number	the MDR complaint fi	iled on Dece It has bee	mber 17, 2013 (Mfr# n determined that one		
Name				additional MDR is no	eeded to acc	ount for the reported		
Address			3. Report Source (Check all that apply)	number of patients a	allegedly in	fected by the scope.		
OLYMPUS MEDICA	L SYSTEM	S CORP.	Foreign		nce these as	sociated complaints:		
		hioji-shi, Tokyo	Study Literature	8010047-2013-00595				
192-8507, Japa	n 			Olympus France investigated the reprocessing practice : the facility. The facility brushed the distal end, the				
Email Address			Health Professional	the facility. The facility instrument channel,	acility brus the suction	hed the distal end, the channel, and the		
4. Date Received by		5.	User Facility	instrument channel	opening with	the same cleaning brush,		
Manufacturer (mm/d		(A)NDA #	Company Representative	which Olympus does instruction manual	of the subje	ct device directs to use		
6. If IND, Give Protoco		IND #	Distributor	the specific cleani:	ng brush for	the distal end and the ch is different from the		
o. In IND, GIVE Protoco	<i></i>	BLA #	Other:	cleaning brush used	for the ins	trument channel and the		
7. Type of Report		PMA/ 510(K) #		suction channel. Ol could not determine	ympus Medica	1 Systems CORP (OMSC)		
(Check all that apply)		Compination		However, improper r	eprocessing	could not be ruled out as		
5-day 🗹 30-d	-	Product Yes		a contributory fact	or to the re	ported event.		
│ ☐ 7-day │ Peric │ 10-day ↓ Initia		Pre-1938 Yes						
	w-up #	OTC Product Yes						
9. Manufacturer Repo	rt Number	8. Adverse Event Term(s)						
8010047-2015-0	0210							
The public reporting burn minutes per response, in sources, gathering and r of information. Send com	den for this co ncluding the ti maintaining th mments regar	ultrements of the Paperwor offection of information has be ime for reviewing instructions the data needed, and completi ding this burden estimate or a gestions for reducing this bu	een estimated to average 66 , searching existing data ng and reviewing the collection any other aspect of this	Department of Health and Huma Food and Drug Administration Office of Chief Information Office Paperwork Reduction Act (PRA) PRASteff@fda.hhs.gov Please DO NOT RETURN this	er Staff	OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number." PRA Staff email address.		

**Erasmus Medical Center Rotterdam, Netherlands** 



Your Vision, Our Future

Date: May 25, 2012 Report Type: Manufacturer Report 8010047-2012-000157

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002



Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event any further correspondence may be directed to my office.

Sincerely,



U.S. Department Food and Drug Ad	of Health and Huma ministration	an Services		For use by u		Mfr Report #	8010047-201	2-00157				
MEDWATCH			importe foi	rs, distributo r MANDAT	rs and manufacturers ORY reporting	UF/Importer Report #						
FORM FDA 350				Page 1	of 15							
A. PATIENT INF	FORMATION				C. SUSPECT PROP	DUCT(S)		FDA Use Only				
1. Patient Identifier		3	. Sex	4. Weight	1. Name (Give labeled stre							
Unk	of Event: Unk		Female	Unk ibs	#1 N/A							
	Date	Unk	Male	or	#2 N/A							
In confidence	or Birth:		<u> </u>	<u>Unk</u> kgs	2. Dose, Frequency & Ro	oute Used	3. Therapy Dat	tes (If unknown, give duration)				
B. ADVERSE E	VENT OR PRODU				#1 N/A		from/to (or be #1	est estimate)				
1. Adverse Even		duct Problem (e.g	., defects/mai	functions)	#2 N/A							
<ol><li>Outcomes Attribut (Check all that application)</li></ol>	ited to Adverse Event ly)				4. Diagnosis for Use (Ind	liaction	#2	vent Abated After Use				
Death:		Disability or I	Permanent Da	amage	#1 N/A	icauon		opped or Dose Reduced?				
Life-threatenin	(mm/dd/yyyy)	Congenital A	nomaly/Birth	Defect			#1 [	Yes No Doesn'i Apply				
Hospitalization	n - initial or prolonged	Other Seriou	is (Important M	Medical Events)	#2 N/A							
Required Inter	rvention to Prevent Perm	anent Impairment/C	Damage (Devi	ces)	6. Lot #	7. Exp. Date		Арріу				
3. Date of Event (mr	m/dd/yyyy)	4. Date of This R	eport (mm/d	d/yyyy)	#1N/A	#1 N/2		vent Reappeared After eintroduction?				
	ary/2012	4	4/26/2012	:	#2N/A	#2 N/A	¥ #1 [	☐ Yes ☐ No ☐ Doesn" Apply				
5. Describe Event or	Problem				9. NDC# or Unique ID		#2 [					
April 201	2, the user fac	ility repor	ted that		10. Concernitent Medical	Braduate and The		🗕 🛄 Арріу				
Pseudomonas a	eruginosa were	identified	from 16 p	patients.	10. Concomitant Medical N/A	Products and The	Irapy Dates (Excl	ude treatment of event)				
The facility	also reported to atients receive	hat the dev	ice was t	tested								
	fore and same b											
sample which	collected from	distal end	the devic	ce. The								
	test for patien ice January 2012				D. SUSPECT MED							
	on the patients.		no addit;	Lonal	1. Brand Name							
					EVIS	EXERA II DUC	DENOVIDEOSC	OPE				
					2. Common Device Name	e DUODENOEND	OSCOPE					
					3. Manufacturer Name, C	ity and State						
					OLYMPUS MEDICAL SY 2951 Ishikawa-cho			8507 Japan				
					4. Model #	Lot #		5. Operator of Device				
					TJF-Q180V	N/A		Health Professional				
					Catalog #	Expiratio	on Date (mm/dd/y					
					N/A Serial #	Other #		Other:				
				1	2101363	N/A						
					6. If implanted, Give Dat	e (mm/dd/yyyy)	7. If Explanted	, Give Date (mm/dd/yyyy)				
evant Tests/La	aboratory Data, Includin	g Dates										
Unk					8. is this a Single-use De	evice that was Rep	rocessed and Re	aused on a Patient?				
					9. If Yes to Item No. 8, E	nter Name and Ad	dress of Reproce	ssor				
					10. Device Available for							
					∐ Yes 🖌 No	Returned to .	Manufacturer on: _	(mm/dd/yyyy)				
					11. Concomitant Medica	Products and Th	erapy Dates (Exc	dude treatment of event)				
7. Other Relevant Hi	istory, Including Preexis moking and alcohol use,	sting Medical Con	ditions (e.g.,	allergies,	N/A							
Unk	moking and aconol use,	nepaliorenai uysio.	1101011, 010.)									
				1	E. INITIAL REPOR	TER						
					1. Name and Address	Phon	ie #					
						L						
					Erasmus Medical	Center,						
					Rotterdam Nether							
1												
Submission of a	report does not co	nstitute an adn	nission that	t medical	2. Health Professional?	3. Occupation		4. Initial Reporter Also Sen				
personnel, user f caused or contrib	acility, importer, di buted to the event.	stributor, man	ufacturer o	r product	Yes 🗌 No	Physician		Report to FDA				

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#### MEDWATCH

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FORM FDA 3500A	(1/09) (continue	əd)	Page 2	of 15		,
F. FOR USE BY U	SER FACILITY/I	PORTER (De		H. DEVICE MANUFAC		2. If Follow-up, What Type?
User Facility 3. User Facility or Impo	Importer			Death     Serious Injury     Malfunction     Other: Potential 3. Device Evaluated by Mani     Not Refurmed to Mani	ufacturer?	Correction Additional Information Response to FDA Request Device Evaluation
4. Contact Person 6. Date User Facility or	7. Type of i	5. Phone Nur	mber 3. Date of This Report		n Summary Attached	January /2011 5. Labeled for Single Use?
Importer Became Aware of Event (mm/	/dd/yyyy)	-up #	(mm/dd/yyyy)	6. Evaluation Codes (Refer t	to coding menual)	Yes 🗹 No
Age of Device	10. Event Problem Co Patient 1735 Device 3190	edes (Refer to coding	g manual)	Method Results Conclusions	67 - 92	) ] ]
11. Report Sent to FDA	?         12. Local           ''''''''''''''''''''''''''''''''''''	Ion Where Event O Iospital Iome Iursing Home Dutpatient Treatment acility Dther:	Outpatient Diagnostic Facility Ambulatory Surgical Facility	Repair 1	Notification Inspection Patient Monitoring	Usage of Device
	CTURERS me/Address (and Man CAL SYSTEMS COI t-cho, Hachiojd	RP.	2. Phone Number 3. Report Source (Check all that apply) Ø Foreign Study Literature Consumer Ø Health Professional	(OMSC) for evaluation investigated by in photograph of the sent from OLYMPUS objective lens. In in it manufacturin From the above in conclusively detection can be considered that the patient and procedure such facility.	t returned to O tion because th ndependent orga distal end of NEDERLAND show n addition ther ng history reco formation only, rmine the cause as a possible infected from o h as environmen	OMSC can not this event. However, it cause of this phenomenon other than the endoscope thal factor in the as a medical device
<ul> <li>4. Date Received by Manufacturer (mm/c 4/26/20</li> <li>6. If IND, Give Protoco</li> <li>7. Type of Report (Check all that apply</li> <li>5-day</li> <li>9. Jo-day</li> <li>9. Manufacturer Repo</li> <li>8010047-2012-0</li> </ul>	(A)ND           011         INE           ol #         STI           PMA           510(k           (a)         Combine           (a)         Combine           (a)         Product           (a)         Pre-19           (a)         OTC F           (b)         OTC F           (b)         OTC F           (c)         State	0 # 1 # () # nation Yes	User Facility     Company     Representative     Distributor     Other:			
minutes per response, in sources, gathering and	ncluding the time for re maintaining the data ne I. Send comments rega	viewing instructions, seded, and completin rding this burden es	ng and reviewing the timate or any other aspect of	Department of Health and H Food and Drug Administratic Office of Chief Information O 5600 Fishers Lane Rockwille, MD 20857 Please DO NOT RETURN t	on Officer (HFA-710)	OMB Statement: "An agency may not conduct or sponso and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number." S.



Your Vision, Our Future

Date: May 26, 2015 Report Type: Manufacturer Report (30day) #8010047.2012.00157

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Dear MDR Coordinator,

Enclosed is a supplemental 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,



Form Approved: OMB	No. 0910-0291,	Expires: 6/30/2015

U.S. Department of Health and Human Services			Form	See OMB statement on reverse
Food and Drug Administration	For use by t	user-facilities, ors and manufacturers	Mfr Report # 8	3D10047-2012-00157
MEDWATCH	for MANDAT	ORY reporting	UF/Importer Re	port#
FORM FDA 3500A (2/13)	Page 1	l of 2		
A. PATIENT INFORMATION				FDÂ Use Onl
1. Patient Identifier 2. Age at Time	3. Sex 4. Weight	C. SUSPECT PRODI 1. Name (Give labeled stren		with a third state of the state
of Event:		#1	gar a manacerery	
or Date	- Female ^{ibs}	#2		
In confidence of Birth:	Male kgs	2. Dose, Frequency & Rou	te Used	3. Therapy Dates (if unknown, give duration)
B. ADVERSE EVENT OR PRODUCT PROBL	EM	#1		fromitio (or best estimate) #1
	(e.g., defects/malfunctions)		<u>.</u> .	
2. Outcomes Attributed to Adverse Event (Check all that apply)		#2 4. Diagnosis for Use (Indica	tion	#2 5. Event Abated After Use
Death: Disability Disability	y or Permanent Damage	#1		Stopped or Dose Reduced?
	ital Anomaly/Birth Defect	#2		#1 🗋 Yes 📄 No 📄 Doesn' Apply
	erious (Important Medical Events)		7. Exp. Date	#2 Yes No Doesn'
Required Intervention to Prevent Permanent Impairme		#1	#1	8. Event Reappeared After
3. Date of Event (mm/dd/yyyy) 4. Date of Th 1/4/2012	is Report (mmlddlyyyy)	#2	#2	Reintroduction?
5. Describe Event or Problem		9. NDC# or Unique ID	<i>π</i> 2	
This supplemental report is being sub				#2 Yes No Doesn
additional information based on the m article that Olympus found on April 2		10. Concomitant Medical P	roducts and The	rapy Dates (Exclude treatment of event)
From January to April 2012, 30 patien Producing Pseudomonas aeruginosa were				
Producing Pseudomonas aeruginosa were of 30 patients had undergone an endos cholangiopancreatography (ERCP) using				(Continue on page 3)
D device. 8 out of 30 patients had not	undergone an ERCP.	D. SUSPECT MEDIC	AL DEVICE	(11111111111111111111111111111111111111
T out of 8 patients without a history in history of ICU stay. The device was i	of ERCP had a	1. Brand Name		
user facility in February 2011. No in		2. Common Device Name		2b. Procode
the device was involved occurred unti device was withdrawn from clinical us		3. Manufacturer Name, City	and State	
5 2012.	e on March 14,			
기 The first patient underwent an ERCP o 기 with the device, and subsequently the	n Tanuary 3, 2012	4. Model #	Lot#	5. Operator of Device
	VIM-2 (Type-B) was			Health Professional
n isolated from patient's blood culture 2012.	on January 4,	Catalog #	Expiration	Date (mmiddlyyyy)
27   27		Serial#	Unique (de	ntifier (UDI) # Other:
24				
	(Continue on page 3)	6. If Implanted, Give Date (/	nmiddlyyyy)	7. If Explanted, Give Date (mm/dd/yyyy)
6. Relevant Tests/Laboratory Data, Including Dates		8. Is this a Single-use Devi	e that was Repr	ccessed and Reused on a Patient?
		Yes No	a blause and the	
		9. If Yes to Item No. 8, Ente	r warne and Addi	ess of Reprocessor
				•
		10. Device Available for Eva	Returned to Ma	,
				(mm/dd/yyyy)
	(Continue on page 3)	Enzymatic cleaner f		apy Dates (Exclude (reatment of event) leaning
<ol> <li>Other Relevant History, Including Preexisting Medical C race, pregnancy, smoking and alcohol use, hepaticlrenal dy.</li> </ol>	onditions (e.g., allergies, sfunction, etc.)			cetic acid as a disinfectant.
				(Continue on page 3)
		E. INITIAL REPORTE	R	
				i '
	j			
		Phone #	Emai	Address
	(Continue on page 3)			-
Submission of a report does not constitute an ac personnel, user facility, importer, distributor, ma		2. Health Professional? 3.	Occupation	4. Initial Reporter Also Sent Report to FDA
caused or contributed to the event.	and a second of product	Yes No		

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FORM FDA 3500		-	Page 2			and a start the start of the st
	USER FA	CILITY/IMPORTER (D 2. UF/Importer F		H. DEVICE MANUF		2. If Follow-up, What Type?
1. Check One User Facility 3. User Facility or Imp	Impo Porter Name <i>l</i>	rier	epon number	Deàth Deàth Serious Injury Malfunction	•	Correction Correction Additional Information Response to FDA Request Device Evaluation
				3. Device Evaluated by M	lanufacturer	4. Device Manufacture Date (mmlyyyy)
4. Contact Person 6. Date User Facility o	ur 17	5. Phone N	8. Date of This Report		tion Summary Atlached o explain why not) or	5. Labeled for Single Use?
Importer Became Aware of Event (mn		Initial Follow-up #	(mmiddlyyyy)	6. Event Problem and Ev	aluation Codes (Refer (d	
9. Approximate Age of Device	_	roblem Codes (Refer to codi	ng manual)	Patient Code Device		
	Patient Code Device Code	<b>–</b> [		Code	~	
11. Report Sent to FD/	A?	12. Location Where Event	Occurred Outpatient Diagnostic Facility Ambulatory	Results	-	
13. Report Sent to Main Yes No(mmidd	<u>.</u>	Nursing Home Outpatient Treatmen Facility Other:	Surgical Facility		lated, Check Type Notification Inspection Patient Monitoring	8. Usage of Device
14. Manufacturer Nam	e/Address			Ciher:		9. If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number:
G. ALL MANUFA 1. Contact Office (and Name Address			2. Phone Number 3. Report Source (Check all that apply) Foreign Study () Literature	subject device, aeruginosa was c strain isolated device. Enteroco site. Environmen the VIM-2 P. aer Gastroenterology a water recipien	journal, the u and clonal rela confirmed for 22 under the force ccus faccium wa tal sampling wa uginosa in four and Repatology t in the endosc	GEH) department and in copy suite. In addition,
Email Address 4. Date Received by		5.	Consumer Health Professional	endemic level. Repair history c	of the device wa	t at the ICU at a low s reviewed by an Olympus
6. If IND, Give Protoco		(A)NDA # _ IND # BLA #	Company Representative Distributor	was repaired one	time in Novemb	d showed that the device per 2011. The device final inspection after
7. Type of Report (Check all that apply) 5-day 30-di 7-day Peric 10-day Inlua 15-day Follo 9. Manufacturer Repo	ay odic 11 w-up # _2	PMA/ 510(k) # Combination Product Yes Pre-1938 Yes OTC Product Yes 8. Adverse Event Term(\$)		related to the p	as the GEH dep atient infectio	the device or artment and the ICU on. The cause of the vely determined.
The public reporting bus minutes per response, in sources, gathering and r of information. Send con	den for this c ncluding the t maintaining ti nments regar	quirements of the Paperword ollection of information has be ime for reviewing instructions, te data needed, and completive ding this burden estimate or a goestions for reducing this bu	en estimated to average 66 searching existing data ng and reviewing the collection ny other aspect of this	Department of Health and J Food and Drug Administrat Office of Chief Information Paperwork Reduction Act PRAStatf@(da.hhs.gov Please DD NOT RETURN	ion Officer PRA) Staff	OMB Statement: "An agency may not conduct or sponsor, and a person is no required to respond to, a collection of information unless it displays a current valid OMB control number." PRA Staff email address.

OCA_0001833

FDA USE ONLY

## Evangelisches Waldkrankenhaus Spandu Berlin, Germany



Your Vision, Our Future

Date: July 10, 2014 Report Type: Manufacturer Report #8010047-2014-00393

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event any further correspondence may be directed to my office.

Sincerely,

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Mfr Report # 8010047-2014-00393

UF/Importer Report #

U.S. Department of Health and Human Services	
Food and Drug Administration	im

MEDWATCH

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For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting
for the a CDATION T reporting

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FDA	Use	Only

	FORM FDA 3500A (1/09)	Page	1 of <b>1</b> 8	5					DA Use Only
	A. PATIENT INFORMATION			SUSPECT PROD					DA USE UNIY
	1. Patient Identifier 2. R. R.		1. N	Name (Give labeled stree	ngth & mfr/labeler)				
			#2	-					
	in confidence B. ADVERSE EVENT OR PRODUC			Dose, Frequency & Rou	te Used	3. Therapy D	Dates (If un	known, gi	ve duration)
		duct Problem (e.g., defects/malfunctions)	#1	1		#1	best estim	310)	
	2. Outcomes Attributed to Adverse Event	duct Problem (e.g., astecis/mailunctions)	#2	2		#2			
	(Check all that apply) Death:	Disability or Permanent Damage	4. (	Diagnosis for Use (India	alion)		Event Aba Stopped o		
	(mm/dd/yyyy)	Congenital Anomaly/Birth Defect	#:	1			Yes		Doesn't
	Hospitalization - initial or prolonged	<ul> <li>Other Serious (Important Medical Events)</li> </ul>	#2				Yes	- No	Doesn't
	Required Intervention to Prevent Perma	anent Impairment/Damage (Devices)		_ot #	7. Exp. Date		Event Rea		Apply
	3. Date of Event (mm/dd/yyyy)	4. Date of This Report (mm/dd/yyyy)	#1		#1		Reintroduc	ction?	Doesn't
	05/26/2014 5. Describe Event or Problem	06/12/2014	#2 9, N	NDC# or Unique ID	#2	#1	Yes	No No	Apply
						#2	Yes 🗌 Yes	No No	Doesn'i Apply
() XINK	Olympus was informed that fo for carbapenem resistant Kle having undergone an endoscop cholangiopancreatography (ER were examined with the same The user facility conducted	bsiella pneumonia after ic retrograde CP) procedure. The patients duodenovideoscope.		Concomitant Medical		rapy Dates <i>(E</i> :	xclude freat	ment of e	vent)
BLACK	endoscope on Jun 3, 2014, an found. The last routine samp	d Klebsiella pneumonia was		SUSPECT MEDIC	CAL DEVICE				
BL	April 29, 2014 did not indic			EVIS E	XERA II DUOI		SCOPE		
USE			2. (	Common Device Name	DUODENOENDO	SCOPE			
PLEASE TYPE OR 1			OL	Manufacturer Name, Ci YMPUS MELICAL SYS 51 Ishikawa-cho,	TEMS COFF.	Tokyo 190	2-6507,	Зарал	
YP				Model #	Lot #		5. (	Operator	of Device
SEJ				F-Q180V Catalog #	N/A Expiratio	n Date (mm/dd	3/vvvvl 🗀	_	Professional
EA				F-Q180V		N/A	1-	Cay Use	er/Palient
ΡĽ				Serial # :02615	Other#				
			1 1	If Implanted, Give Date	(mm/dd/yyyy)	7. If Explant	ed, Give D	ate (mm/c	d/yyyy)
	6. Relevant Tests/Laboratory Data, Including	g Dates		N/A Is this a Single-use Dev	vice that was Rep	N/A rocessed and	Reused or	a Patien	1?
				Yes 🖌 No If Yes to Item No. 8, En					
Ć			9. N/		ter Name and Ado	ress of Repro	cessor		
				Device Available for E	valuations /ha	leand to EDAL			
			1 1 .	Yes No	Returned to N		0.0	6/12/20	014
				Concomitant Medical	Products and The	rapy Dates (F		mm/dd/yy	
	7. Other Relevant History, Including Preexis	ting Medical Conditions (e.g., ellergies,							,
	race, pregnancy, smoking and alcohol use, i	hepatic/renal dysfunction, etc.)							
				INITIAL REPORT	ER				
			1.	Name and Address	Phone	a #			
					·				
				vangelisches Wa adtrandstraße					
	Submission of a report does not cor	stitute an admission that medical	┙┝	Health Professional?	3 Occupation		4 In#	al Report	er Also Sent
	Submission of a report does not cor personnel, user facility, importer, dis caused or contributed to the event.	stributor, manufacturer or product			hysician		Rep	ort to FD/	

#### MEDWATCH

FDA USE ONLY

FORM FDA 3500/	A (1/09)	(continued	D)				Page	2 of	15									
F. FOR USE BY L	JSER F/					_			H. DEVICI			TUR	ERS	ON	LY			
1. Check One	<b>—</b>	1	2. UF/	Importer R	eport Ni	um	hber		. Type of Re	-	/ent					2. If Follow-		/pe?
User Facility Importer 3. User Facility or Importer Name/Address									☐ Death √ Serio								rection ditional Inform	nation
3. User Facility or impo	orter Name	erAduress							✓ Sello								sponse to FD	
									C Other								vice Evaluati	
									During Fig			6 l v				4. Device M	anufacture	Data
								ľ	Device Eva	Returned to N						(mm/yyyy		Date
4. Contact Person			Į.	. Phone N	mber		=		[_] Not P [√] Yes	Evalua				Attache	d	03/2012		
4. Contact Person										Alfach page I					-	5. Labeled (	for Single U	se?
6. Date User Facility of	r	7. Type of Re	port				f This Report	11	provi	ide code:						∏ Ye	s 🔽 t	٩o
Aware of Event (mm	v/dd/yyyyy)	Initial			(mm	/00	d/yyyy)											
		Follow-u	o#						. Evaluation	n Codes (Rei	fer lo	coding	g ma	nual)				
9. Approximate	10. Event	Problem Cod	_	efer to codi	ng manu	al)				Method		10	-	3	8	-		
Age of Device	Patient			<b>_</b>		Г				Results		142	ן_ר					
	Code	1735				- [				Results	_	142				ļ	_ <u>_</u>	
	Device Code	2303		1	-	-			c	onclusions		51				-		
11. Report Sent to FD/	47	12. Locatio	n Wł	ere Event	Occurre	d		1	. If Remedia	al Action Ini	itiate	d, Che	ck T	уре	8.	Usage of De	vice	
T Yes		🛛 🖓 Но	spital				tpatient agnostic Facility		🗌 Reca	all [	N	otificati	ion				Use of Devic	e
No (mm/dd	(XYYYY)	□ Ho				Aπ	nbulatory		C Repa	air [	In	spectio	n			🖌 Reuse		(
13. Report Sent to Mar	nufacturer		-	Home nt Treatmer		Su	irgical Facility		Repl	ace [	_	alient N		-		Unkno		under
Yes			cility	nt Treatmen	n				🗌 Rela	beling [		lodifica djustmi			3.	21 USC 360ii removal rep	(f), list corre	ction/
No (mm/dd	VYYYY)	[] 08	ner: _		(Spec	cifu	/		C Othe	er:					_	removarrep	and a second	
14. Manufacturer Nam	e/Address	5			(			11							_			
									10. 🖌 Addi	itional Manu	fact	urer Na	arrat	ive	ar	nd / or	11. 🗌 Corr	rected Data
G. ALL MANUFACTURERS         1. Contact Office - Name/Address (and Manufacturing Site for Devices)         OLYMPUS MEDICAL SYSTEMS CORP.         2951 Ishikawa-cho, Hachioji-shi, Tokyo         192-8507, Japan         4. Date Received by Manufacturer (mm/dd/yyyy)         07/01/2014         5. MIND, Give Protocol #         STN #         PMA/					po ore lud iter on ea se ist	dy rature Isumer Ilth Professional Ir Facility Inpany presentative tributor		SE & CO. confirme instrume on the s The exac conclusi report w informat Please c other th	KG (OE) d brown ent chan suction of t cause vely de vill be tion bec tross-re pree pat	KG) st cha cha ter sub come	for ain . In nnel use mine mitt s av ence ts:	ev and r's d a ed ail th 801	alua bla diti rep t th if s table ne fo 10047	ort ick ort is sign 2 1a 0110 7-20	urned to n. The ev foreign m there wa could no time. A s ificant a ter. wing repo 14-00407 2014-0040	valuatio material as black bt be suppleme and addi orts for	n on the stain ntal tional	
9. Manufacturer Repo 8010047-2014-0	day al ow-up # ort Numbe 00393		ation 3 aduct se Ev	Yes Yes Yes Yes ent Term(s					Department	of Washings	4 1-1		ande	ar		OMB Staten	nenf-	
The public reporting but minutes per response, i sources, gathering and collection of information this collection of information	including th maintainin n. Send cor	he time for revie ng the data nee mments regard	wing ded, a ing th	instructions and complet is burden e	s, search ing and r stimate o	rev or a	g existing data viewing the any other aspect		Department Food and Dr Office of Chi 5600 Fishers Rockville, M	ug Administr ef Informatio s Lane	ration					"An agency i	may not con	duct or spons red to respon ation unless it OMB control

sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Please DO NOT RETURN this form to this address.

or, d and a person is not required to respon-to, a collection of information unless it displays a currently valid OMB control number."

## Fox Chase Cancer Center, Philadelphia, Pennsylvania

U.S. Department of Health and Human Services Mfr Report # 2431293-2015-00007 For use by user-facilities, Food and Drug Administration importers, distributors and manufacturers UF/importer Report # tor MANDATORY reporting MedWatch Page 1 of 2 FORM FDA 3500A (2/13) FDA Use Only A. PATIENT INFORMATION C. SUSPECT PRODUCT(S) 1. Name (Give labeled strength & mfr/labeler) 3. Sex 4. Weight 1. Patient Identifier 2. Age at Time of Event: ib: Female OF. or Date #2 Mate In confidence of Birth kgs Therapy Dates (If unknown, give duration) from/to (or best estimate) 2. Dose, Frequency & Route Used 3 **B. ADVERSE EVENT OR PRODUCT PROBLEM** #1 Adverse Event and/or Product Problem (e.g., defects/malfunctions) #2 #2 2. Outcomes Attributed to Adverse Event (Check all that apply) 5 Event Abated After Use 4. Diagnosis for Use (Indication) Stopped or Dose Reduced? Death: Disability or Permanent Damage (mm/da/y/yy) Doesn' #1 🗌 Yes 🗌 No Apply Life-threatening Congenital Anomaly/Birth Defect #2 Doesn' Hospitalization - initial or prolonged Other Serious (important Medical Events)  $\Box$ #2 Yes No 6. Lot# 7. Exp. Date Apply Required Intervention to Prevent Permanent Impairment/Damage (Devices) 8. Event Reappeared After #1 #1 **Reintroduction?** 3. Date of Event (mm/dd/yyyy) Date of This Report (mm/dd/yyyy) #1 🗌 Yes 🗌 No #2 #2 Doesn 06/05/2015 Apply 9. NDC# or Unique ID 5. Describe Event or Problem Doesn' #2 Yes No As reported by the customer: Sometime between 04/21/2015 and 05/06/2015, the subject 10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) endoscope was cultured and tested positive for Klebsiella Pneumoniae. ¥z (Continue on page 3) ACK D. SUSPECT MEDICAL DEVICE 1. Brand Name Fuiinon В 2b. Procode 2. Common Device Name щ 78F--DT Endoscope 3. Manufacturer Name, City and State Eujifilm Optics Co., Ltd. Mito Factory ð 4112 Tono, Hitschiomiya City, Japan 319-2224 PLEASE TYPE 5. Operator of Device 4. Model # Lot # ED-530XT Health Professional Catalog # Expiration Date (mm/dd/yyyy) Lay User/Patient Other: Serial # Unique Identifier (UDI) # ND102A064 6. If Implanted, Give Date (mn1/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy) (Continue on page 3) 6. Relevant Tests/Laboratory Data, including Dates 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? V No Yes 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor 10. Device Available for Evaluation? (Do not send to FDA) 05/22/2015 🖌 Yes 🗌 No Returned to Manufacturer on: (mm/dd/yyyy) 11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (Continue on page 3) Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (Continue on page 3) E. INITIAL REPORTER 1. Name and Address Fox Chase Cancer Center 333 Cottman Ave. Philadelphia, PA 19111 Phone # Email Address (Continue on page 3) Initial Reporter Also Sent Submission of a report does not constitute an admission that medical 2. Health Professional? 3. Occupation Report to FDA personnel, user facility, importer, distributor, manufacturer or product Physician 2 Yes 🗌 No 🗋 Yes 🗌 No 🖌 Unk caused or contributed to the event.

FUJIFILM0000332

### **MEDWATCH**

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FDA USE ONLY

FORM FDA 3500	A (2/13) (d	continuec	1)	Page 2	? of 2		
F. FOR USE BY	USER FAC	LITY/M	PORTER (C	evices Only)	H. DEVICE MANU	FACTURERS ONLY	
1. Check One			. UF/Importer I		1. Type of Reportable i		2. If Follow-up, What Type?
User Facility	Importer				Death		
3. User Facility or Importer Name/Address					Serious injury		Additional Information
					Malfunction		Response to FDA Request
							Device Evaluation
					3. Device Evaluated by	Manufacturer?	<ol> <li>Device Manufacture Date (mm/yyyy)</li> </ol>
					Not Returned to	Manufacturer	,
4. Contact Person			5. Phone N	umber	🖌 Yes 🗌 Eval	uation Summary Attached	12/21/2011
						e to explain why not) or	5. Labeled for Single Use?
6. Date User Facility o	vr 7.	Type of Re	port	8. Date of This Report	provide code:		Yes 🗸 No
Importer Became Aware of Event (mn	n/dd/yyyy)	nitial		(mm/dd/yyyy)			_
			<b>.</b> #		6. Event Problem and E	valuation Codes (Refer to a	coding manual)
	L`	Follow-u	es (Refer to codi	na maawa()	Patient	3190 -	_
9. Approximate Age of Device	IU. Event Pr	robiem Code	es (reler to cou	ng manuar)	Code		
	Patient Code		-	-	Device Code	2895 -	2303 - 1091
	Device				1		
	Code			-	Method	10 ~	
11. Report Sent to FD/	A7	12. Locatio	n Where Event	Occurred	Results	142 -	
Yes		Hos	spital	Outpatient	Results		
	/yyyy)	Hor	ne	Diagnostic Facility	Conclusions	18 - 61	-
13. Report Sent to Mar	nufacturar?	Nur	sing Home	Ambulatory Surgical Facility	7. If Remedial Action In	itiated Check Type	Usage of Device
			patient Treatme	nt			Initial Use of Device
Yes(mm/dd	(yyyy)	Fac			Recall	Notification	Reuse
No ,			er:	(Specify)	Repair		Unknown
14. Manufacturer Nam	e/Address			,	Replace	Patient Monitoring	If action reported to FDA under
					Relabeling	Modification/ 9 Adjustment	21 USC 360i(f), list correction/ removal reporting number:
I					Other:		isnova reporting number.
					· · · · ·		
					10. 🖌 Additional Man		nd / or 11. Corrected Data
G. ALL MANUFA							rom Fujifilm Medical
1. Contact Office (and	Manufacturii	ng Site for D	)evices}	2. Phone Number			ed the facility as a status is unknown and
Name							gating. It is believed
Address				3. Report Source (Check all that apply)		which had multid	
Fujifilm Medica				Foreign		• •	exposed to the endoscope
10 Kigh Point H	Drive, Wa	ayne, NJ	07470	Study	by the endoscop		e patients were infected
Fujifilm Optics	s Co., Lt	d. Mito	Factorv	Literature	by the endoscop	Ξ.	
4112 Tono, Hita					Three subsequen	t contact attempt.	s on 05/19/2015,
Email Address				Health Professional			ade to the facility's
				User Facility		ient Safety regard	ding condition of ct endoscope. As of
<ol> <li>Date Received by Manufacturer (mm/d)</li> </ol>	d/yyyy)	5.		Company			een provided by the
05/06/20	015	(A)NDA #		Representative	facility.		4
6. If IND, Give Protoco		IND #		Distributor			
	• •F	BLA #		Other:			cope was received at py Division and placed
		PMA/				The customer state	
<ol> <li>Type of Report (Check all that apply)</li> </ol>		510(k) #	K042076		shipment to Fuj	ifilm, the subject	t endoscope was high
5-day V 30-da	1	Combinatio Product	on ∏Yes				ly tested negative on
7-day Perio		ł			two occasions. shipment to Fuj		s sterilized prior to
10-day Initial		Pre-1938	Yes		snipment to Fuj	T T T T #15 '	
15-day Follow		OTC Produ	ict 🗌 Yes	·			
9. Manufacturer Repor	t Number	8. Adverse	Event Term(s)	J			
2431293-2015-0	1		(-)				
240122013-00	5007				,		
·							
			-	Reduction Act of 1995.	Department of Health and Food and Drug Administra		OMB Statement: "An agency may not conduct or sponsor, and a person is not
The public reporting burd minutes per response, in				en estimated to average 66 searching existing data	Office of Chief Information	Officer	required to respond to, a collection of

sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: CONFIDENTIAL

# Froedtert Hospital Milwaukee, Wisconsin



August 15, 2014

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,

Copies:

Form Approved: OMB No	. 09	10.029 1	. Expires	12/31/11
	300	OMB stat	ement or	reverse

U.S. Department of H Food and Drug Admin		an Services	importe	For use by u	ser-facilities, 15 and manufacturers	Mir Depart #	2951238-201		I, Expires 12/31/11 lement on reverse
MEDWATCH			for	r MANDAT	ORY reporting	UF/Importer Re	# hoqe		
FORM FDA 3500A	(1/09)			Page 1	of <u>2</u>		÷		FDA Use Only
A. PATIENT INFOR					C. SUSPECT PROD	UCT(S)	-	·	TOX 030 Only
1. Patient identifier 2.	Age at Time		3. Şex	4. Weight	1. Name (Give labeled stre	ngth & mîr/labeler)	1		
	of Event: or		📋 Female	ibs	#1				
	Date of Birth:		🛄 Male	or kgs	#2				
B. ADVERSE EVE		CT PROBLE	vi		2. Dose, Frequency & Ro	ute Used	3. Therapy Da from/to (or b	ates (if unknowi best estimate)	n, give duration)
1. Adverse Event	and/or 🗌 Pro	oduct Problem (e	.g., defects/mai	functions)	<u>#1</u>	<u></u>	#1	<u> </u>	
2. Outcomes Attributed (Check all Ihat apply)	o Adverse Event				#2		#2	wort Abatad B	<b>A</b> le 1 16 e
Death:		Disability o	r Permanent Da	amage	4. Diagnosis for Use (Indi #1	cation)	S	Event Abated A Stopped or Dos	e Reduced?
Life-threatening	nm/dd/yyyy)	 Congenilat	Anomaly/Birth	Defect	#2		#1		to Doesn't Apply
Hospitalization - In	ilial or prolonged	Other Serie	ous (important l	Medical Events)	#2 6, Lot#	7. Exp. Date	#2		No Doesn't
	tion to Prevent Perm				#1	#1		Event Reappea Reintroduction	
3. Date of Event (mm/dd	<i>'</i> YYYY)	4. Date of This	Report (mm/d	a/yyyy)	#2	#2		Yes [] t	No Deesn'i
5. Describe Event or Pro	blem	-I			9. NDC# or Unique ID				Apply
					10. Concomitant Medical		,		
					3. Manufacturer Name, C 4. Model# Catalog#	Lot #	ion Date <i>(mm/d</i> d	He He	ator of Device alth Professional
					Serial #	Other	<u>.</u>	Пон	y User/Palient her:
					6. If Implanted, Give Dat	e (mm/dd/yyyy)	7. If Explant	ed, Give Date (i	mm/dd/yyyy)
<ol> <li>Relevant Tests/Labor</li> <li>Relevant Histo race, pregnancy, smol</li> </ol>			onditions (e.g. stunction, etc.)	allergies,	8. Is this a Single-use D Yes No 9. If Yes to Item No. 8, E 10. Device Available for Yes No 11. Concomitant Medica	nter Name and A Evaluation? (Do Returned to I Products and T	ddress of Repro not send to FDA) Manufacturer or	) ) n:(mm/	dd/yyyy)
					E. INITIAL REPOR 1. Name and Address		one #		<u> </u>
Submission of a rep personnel, user fac	ort does not co lity, Importer, c ed to the event	distributor, ma	- dmission th anufacturer	at medical or product	2. Health Professional?	3. Occupation		Report t	aporter Also Ser o FDA No 💽 Uni

#### MEDWATCH

	•		Da	of 2		
FORM FDA 3500	A (1/09) (d	continued)	Page 2	·		
	USER FAC	CILITY/IMPORTER (De		H. DEVICE MANUFA		,
1. Check One		2. UF/Importer Re	port Number	1. Type of Reportable Even	it	2. If Follow-up, What Type?
User Facility	lmport			Death		X Correction
3. User Facility or Imp	orter Name/A	ddress		Serious injury		Additional Information
				Malfunction		Response to FDA Request
				Other:		Device Evaluation
				3. Device Evaluated by Mar	nufacturer?	4. Device Manufacture Date
				Not Returned to Mar		(mavyyyy)
4. Contact Person		5. Phone Nu	mber		on Summary Attached	
				No (Attach page to e	-	5. Labeled for Single Use?
6. Date User Facility o	er 7.	Type of Report	8. Date of This Report	provide code:		Yes No
Importer Became Aware of Event (mm	vadyyyy)   [	Initial	(mm/dd/yyyy)			
]		Follow-up #		6. Evaluation Codes (Refer	to coding manual)	
9. Approximate		oblem Codes (Refer to codin	o menuel)	Method	10 - 23	- 37 - 3264
Age of Device	i					
	Pallent Code	-		Results	3251 -	
	Device				75 -	
	Code	J [¯] [	J [_] [	Conclusions		
11. Report Sent to FD/	A7	12. Location Where Event C		7. If Remedial Action Initiat	ted, Check Type	B. Usage of Device
Yes(mm/dd	(4000)	Hospital	Outpatient Diagnostic Facility	Recall 🗍	Notification	Initial Use of Device
	(1)(1)	Home	Ambulatory		inspection	Reuse
13. Report Sent to Mar	nufacturer?	Nursing Home Outpatient Treatment	Surgical Facility		Patient Monitoring	Unknown
Yes		Facility	•	Relabeling	Modification/ Adjustment	9. If action reported to FDA under 21 USC 3601(f), list correction/
	(1/1/1/	Other:	(Decelle)	Other:		removal reporting number:
14. Manufacturer Nam	e/Addreen		(Specify)			
i in manufactarat yanı I	WAR1033					
1				10. Additional Manufac		and /or 11. 🖌 Corrected Data
1					-	ng submitted to correct of 2951238-2014-00041.
				The correct MFR R	•	
				2951238-2014-0002	3. See sectio	n G9.
G. ALL MANUFA				As part of our in	vestigation in	to this report the device
1. Contact Office - Nai for Devices)	me/Address (	and Manufacturing Site	2. Phone Number			site laboratory for
	•			microbiological t		
			3. Report Source (Check all that apply)			device was then forwarded
			Foreign	to Olympus for ph	Norcar evernat	10111
			Study			pus for evaluation. The
			Literature	•		e evaluation found no
			Consumer			confirm the reported f bio-materials in the
			Health Professional	device. The devic		hed and returned to the
4. Date Received by		5.	User Facility	user facility.		
Manufacturer (mm/c	dd/yyyy)	(A)NDA #	Company Representative			
08/11/2	014		Distributor			
6. If IND, Give Protoco	ol #		Other:			
		STN #				
7. Type of Report (Check all that apply)		- PMA/ 510(k) #				
		Combination				
5-day 🗸 30-d	-	Product Yes				
7-day Perio		Pre-1938 🛄 Yes				
	₩ ₩-υp#_2	OTC Product 🔲 Yes				
9. Manufacturer Repo		8. Adverse Event Term(s)	l	4		
		A WAARIOG PADIC LOUNGS				
2951238-2014-0	10023					
				] [		
The public reporting bur	den for this co	direction of information has be me for reviewing instructions,	en estimated to average 66 searching evicting data	Department of Health and H Food and Drug Administration	luman Services	OMB Statement; *An agency may not conduct or sponsor.
sources, gathering and r	maintalning th	e data needed, and completing	g and reviewing the	Office of Chief Information C		and a person is not required to respond to, a collection of information unless #
		ents regarding this burden est g suggestions for reducing this		1350 Piccard Drive, 420A Rockville, MD 20850		An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Rockville, MD 20850 Please DO NOT RETURN this form to this address.

FDA USE ONLY



January 28, 2014

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,



Copies:

				Approved: OMB NO. C	e OMB statement on reverse.	
U.S. Department of Health and Human Service Food and Drug Administration	importers, distributor	s and manufacturers		951238-2014-0	0023	
EDWATCH for MANDATO		ORY reporting	UF/Importer Report #			
FORM FDA 3500A (1/09)	Page 1 d	of			FDA Use Only	
A. PATIENT INFORMATION  A. Patient Identifier  In confidence  B. ADVERSE EVENT OR PRODUCT PRO  Contromes Attributed to Adverse Event  Contomes Att	OBLEM oblem (e.g., defects/mailunctions) isability or Permanent Damage ongenital Anomaly/Birth Defect ther Serious (Important Medical Events) mairment/Damage (Devices) of This Report (mm/dd/yyyy) 01/06/2014 ttients tested positive acteriaceae containing (CRE-NDM) after having le procedure. The patients movideoscope. Dii was found in the 2013 that patient action subsequently 0, 2013 resistant E. Dile duct fluid. The inspecified amount of went back to India. Tas dispatched to the service has not been	C. SUSPECT PRODU 1. Name (Give labeled streng #1 #2 2. Dose, Frequency & Rout #1 #2 4. Diagnosis for Use (Indice #1 #2 6. Lot # #1 #2 9. NDC# or Unique ID 10. Concomitant Medical Pr 10. SUSPECT MEDIC 1. Brand Name Olympus 2. Common Device Name D 3. Manufacturer Name, City OLYMPUS MEDICAL SYST 2951 Ishikawa-cho, B 4. Model # TJF-Q180V Serial# 2101529 0. If Implanted, Give Date (IN/A)	th & mtnTabeler) a Used tion) 7. Exp. Date #1 #2 oducts and There AL DEVICE EVIS EXERA uodenovideo and State EM CORPORATI tachioji-shi, Lot# N/A Expiration Other # N/A	from/to (or best ex #1 #2 5. Event a Stoppe #1	Abated After Use ad or Dose Reduced? ies No Doesn't Apply Reappeared After oduction? ies No Doesn't Apply res No Doesn't Apply ies No Doesn't Apply ies No Doesn't Apply ies No Doesn't Apply ies No Doesn't Apply ies No Doesn't Apply ies Content of event) ideoscope 7. Japan 5. Operator of Device [] Health Professional Lay User/Patient ] Other: ve Date (mm/dd/yyyy)	
Other Relevant History, including Pressisting Mer race, pregnancy, smoking and elcohol use, hepation on-Hodgkin's Lymphoma, chemo, S/ tem cell transplant (4/18/13), p BD dialation, MRCP shows some bi	dical Conditions (a.g., alfergias, renal dystunction, etc.) P autologous peripheral rior cholecystectomy,	<ul> <li>B. is this a Single-use Davi Yes Vo</li> <li>Yes Vo</li> <li>H Yes to item No. 8, Enterno</li> <li>N/A</li> <li>10. Device Available for Ev</li> <li>Yes Vo</li> <li>Yes Vo</li> <li>11. Concomitant Medical P</li> <li>Scope Buddy Model A</li> <li>Medivators scope W</li> <li>E. INITIAL REPORT</li> <li>1. Name and Address</li> <li>Froedert Hospital</li> <li>2900 W. Wisconsin</li> <li>Milwaukee, WI 532</li> </ul>	aluation? <i>(Do not</i> Returned to M roducts and The sn# unk asher model/ IR Phone Avenue	ress of Reprocesso send to FDA) anufacturer on: rapy Dates <i>(Exclude</i> (sn# unk	r (mm/dd/yyyy)	
bmission of a report does not constitute reonnel, user facility, importer, distribute used or contributed to the event.	an admission that medical or, manufacturer or product	2. Health Professional? 3	. Occupation sk Manager	4.	Initial Reporter Also Sent Report to FDA Yes No • Unk.	

PLEASE TYPE OR USE BLACK INK

OCA_0000831

MEDWATCH					_	EDA UŜË ONLY
FORM FDA 3500		continued)	Page	2 of ²		
F. FOR USE BY			R (Devices Only)	H. DEVICE MANUFACT	URERS ONLY	
1. Check One			rter Report Number	1. Type of Reportable Event		2. If Follow-up, What Type?
User Facility	[] Impor		<u> </u>	Death		Correction
3. User Facility or Imp	orter Name//	Address		Serious Injury		Additional Information
				Melfunction		Response to FDA Request     Device Evaluation
				3. Device Evaluated by Manufa		<ol> <li>Device Manufacture Data (mm/yyyy)</li> </ol>
4. Contact Person		5 Phr	ne Number	Ves Evaluation Su		unk
				No (Attach page to expla provide code;	•	5. Labeled for Single Use?
6. Date User Facility o	r 7	. Type of Report	8. Date of This Report (mm/dd/yyyy)	provide code:		Yes 🗸 No
Aware of Event (mm	vdd/yyyy)	lebini	(minudayyyy)			
		Follow-up #		6. Evaluation Codes (Refer to co	oding menual)	,, <b></b> ,
9. Approximate Age of Device	10. Event P	roblem Codes (Refer to	coding manual)	Method		
Age of Device	Patient	1735 -		Results		
	Code					
	Code	2993 -			·• -	]•[]·[]
11. Report Sent to FDA	17	12. Location Where E		7. If Remedial Action Initiated,		Usage of Device
Yes(mm/dd	1000)	Hospital	Outpatient Diagnostic Facility	Recali Notif	1	Initial Use of Device
∐ No		Nursing Home	Ambulatory Surgical Facility	Repair Insp	ection ent Monitoring	Unknown
13. Report Sent to Man	iulacturer7	Outpatient Tre			9	If action reported to FDA under
Yes(mm/dd/	www	Facility		Adju	Inerateu	21 USC 360)(1), list correction/ removal reporting number:
No No			(Specify)	Other:		
14. Manufacturer Name	e/Address			10. 📝 Additional Manufacture		d / or 11. Corrected Data
G. ALL MANUFA 1. Contact Office - Nan for Devices; OLYMPUS AMERI 2400 Ringwood San Jose, CA OLYMPUS MEDIC 2951 Ishikawa	ne/Address( CA, INC Avenue 95131 AL SYSTE	and Menufacturing Si	3. Report Source (Check all that apply) Foreign Sludy	exact cause of the u conclusively determi report will be submi information becomes Please cross-referen other four patients: 2951238-2014-00027.	ined at this i itted if addit available lat nce the follow : 2951238-201	time. A supplemental tional and significant ter. wing reports for the 4-00024,
192-8507, Jap	an		Health Professional			
4. Date Received by Manufacturer (mm/d	d/www	5.	User Facility			
01/06/20		(A)NDA #	Company Representative			
6. If IND, Give Protoco	#	IND #	Distributor			
		STN #				
7. Type of Report (Check all that apply) 5-day 9 30-da 7-day Perio 10-day 9 Initial 15-day Follow	ay dic w-up #	PMA/ 510(k) # Combination Product Pre-1938	/es	-		
2951238-2014-0	0023		rm(s) as been eslimated to average 66	Department of Health and Human	n Servicea	OMB Statement:
minutes per response, in sources, gathering and n	cluding the ti naintaining th Send commo	me for reviewing instruc e data needed, and cor ents regarding this burd	tions, searching existing data npleting and reviewing the en estimate or any other aspect o	Food and Drug Administration Office of Chief Information Office	ır	"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

OCA_0000832

# Hartford Hospital Hartford, Connecticut



May 22, 2014

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,

Copies:

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11

						Poin		See OMB stateme	
	J.S. Department of food and Drug Adm		an Services	For use by u	ser-facilities, rs and manufacturers	Mfr Report # 2	951238-20	14-00174	
I	MEDWATCH	l		for MANDAT	ORY reporting	UF/Importer Re	port #		
1	ORM FDA 3500	A (1/09)		Page 1	of <u>2</u>			F	DA Use Only
	A. PATIENT INFO				C. SUSPECT PRODU	JCT(S)			•
	1. Patient Identifier 2			3. Sex 4. Weight	1. Name (Give labeled streng				
	. Padencidenciner 2	of Event:		J. dex 4. Height		gin a minizeriory			
		or		Female Ibs	#1				
		Dete		Mele for	#2				
L	In confidence	of Birth:		×ys	2. Dose, Frequency & Rout	te Used	3. Therapy D	ates (If unknown, gi	ve duration)
	B. ADVERSE EVI	ENT OR PRODUC	CT PROBLEM	и 			#1	best estimate)	
_  -	. 🔽 Adverse Event	and/or 🗍 Pro	duct Problem (e.	g., defects/malfunctions}	#1		•		
- L	2. Outcomes Attribute				#2		#2		
	(Check all that apply)				4. Diagnosis for Use (Indice	ation)		Event Abated After	
	Death:	(mm/dd/yyyy)	Disability o	r Permanent Damage	#1			Stopped or Dose R	Doesn't
	Life-threatening		Congenital	Anomaly/Birth Defect			[*'	Yes No	
	Hospitalization -	initial or prolonged	Other Serie	ous (Important Medical Events)	#2	The Date	#2	Yes No	Doesn't
	<u> </u>	ention to Prevent Perma			6. Lot#	7. Exp. Date			
ŀ				Report (mm/dd/yyyy)	#1	#1		Event Reappeared Reintroduction?	Atter
ľ	Date of Event (mm/r 01/27	/2014	1	05/02/2014	#2	#2	I *		Doesn't
ŀ					9. NDC# or Unique ID				
	Describe Event or P Diympus was in:		elve paties	nts tested			#2	📋 Yes 🗌 No	Doesn't Apply
_  ı	positive for E	scherichia col	i (E. coli)	containing	10. Concomitant Medical P	roducts and The	apy Dates (Ex	clude treatment of e	
				after having					
	indergone an e	• • • • • • • • • • • • • • • • • • • •							
	cholangiopanci cultures were :		•	ure. The positive					
				e examined with					
	four different								
-	duodenovideosco	•		by the user	D. SUSPECT MEDIC	AL DEVICE			
L P	facility. No o	rganisms were	isolated.					enovideoscop	9
	On January 27,	2014, the fir	st natient	underwent an	2. Common Device Name				
				reportedly tested			oscope		
	positive for re				<ol> <li>Manufacturer Name, Cit oLYMPUS MEDICAL SYST</li> </ol>	y and State TEM CORPORATI	ON		
	information was	s available.			2951 Ishikawa-cho,	Hachioji-shi,	Tokyo 192	-8507, Japan	
TYPE					4. Model #	Lot #		5. Operator	of Device
21					TJF-Q180V	N/A		[7] Health	Professional
IJ					Catalog #	Expiratio	n Date (mm/dd		er/Patient
PLEASE					TJF-Q180V		Unk	Other:	
31					Serial #	Other#			
-					2304031		7 If Evolent	ed, Give Date (mm/	drihoons)
					<ol> <li>If Implanted, Give Date ( N/A</li> </ol>		N/A		
ē	Relevant Tests/Labo	oratory Data, Includin	g Dates		8. is this a Single-use Dev	ice that was Rep	1	Reused on a Patier	nt?
					Yes 📝 No				
					9. If Yes to Item No. 8, Ent	er Name and Add	ress of Repro	Cessor	
					N/A				
					10. Device Available for Ex				
					🗌 Yes 🖌 No	Returned to M	anufacturer on	(mm/dd/y	()
					11. Concomitant Medical F	Products and The	rapy Dates /E		
L				1111	Custom Ultrasonics				-
7	<ul> <li>Other Relevant Hist race, pregnancy, smooth</li> </ul>	ory, including Preexis oking and alcohol use, i	uting Medical Co hepatic/renal dvs	nditions (e.g., allergies, function, etc.)					
E	ile duct obst								
					E. INITIAL REPORT	ER			
					1. Name and Address	Phone	e #		
						l			
					Name ford Handler				
					Hartford Hospital 80 Seymour Street				
					Hartford, CT 0610				
				1					
									An Alex Ar
5	ubmission of a re	port does not cor	nstitute an ad	mission that medical	2. Health Professional?			4. Initial Report Report to FI	ter Also Sen )A
p	ersonnel, user fac aused or contribu	cility, importer, di	stributor, mai	nufacturer or product	Yes No A	dministrator/Su	pervisor	Yes 🗌	No 💽 Unk.
	avagu ur cuntriQU	TAR TO THE GAGHE							

MEDWATCH	1						FDA USE ONLY
FORM FDA 3500		continued)		Page	2 of ²		
F. FOR USE BY	, ,,				H. DEVICE MANUFAC		
1. Check One		2. U		teport Number	1. Type of Reportable Event		2. If Follow-up, What Type?
3. User Facility or Imp	orter Name/A	Address			Serious Injury		Additional Information
					Matfunction		Response to FDA Request
					Other:		Device Evaluation
					3. Device Evaluated by Man		<ol> <li>Device Manufacture Date (mn/yyyy)</li> </ol>
4. Contact Person			5. Phone N	umber	Not Returned to Manu	n Summary Attached	unk
					No (Attach page to e	•	5. Labeled for Single Use?
6. Date User Facility o Importer Became Aware of Event (mm		. Type of Repor	t	8. Date of This Report (mm/dd/yyyy)	provide code:		TYes 🖌 No
		Follow-up #			6. Evaluation Codes (Refer to	to coding manual)	
9. Approximate Age of Device		roblem Codes (i		ng manual)	Method		
Age of Device	Patient	1735	• [		Results		
	Code						┍╜└──╓ <mark>╓╓</mark> ┙╵┶───┚
	Code	2993 -	·[		Conclusions	20 -	
11. Report Sent to FD/	A?	12. Location W		Occurred	7. If Remedial Action Initiate		Usage of Device     Initial Use of Device
☐ Yes(mm/dd	(	Hospita	1	Diagnostic Facility		Notification	Reuse
13. Report Sent to Mar	nufacturer?		Home	Ambulatory Surgical Facility		Patient Monitoring	Unknown
∏ Yes		Outpati Facility	ent Treatmer	u			9. If action reported to FDA under 21 USC 360i(f), list correction/
No (mm/dd	(yyyyy)	Other:		(0	Other:	Rajustment	removal reporting number:
14. Manufacturer Nam	e/Address			(Specify)			
					10. 🖌 Additional Manufact	turer Narrative a	and / or 11. Corrected Data
							eport has not yet been
					returned to Olympu	is for evaluati	ion.
					-	-	th this report, Olympus
G. ALL MANUFA			1 0:				r facility to observe the actices. There were minor
1. Contact Office - Nar for Devices)	me/Address (	and Manufactui	nng Site	2. Phone Number			rocessing of the device.
OLYMPUS AMERI	CA, INC			3. Report Source			lity had no suction in taff were not using a
2400 Ringwood San Jose, CA				(Check all that apply)	syringe to flush a	around the ford	ceps elevator riser area.
San Jose, CA	55151			Sludy	The exact cause of	the user's ex	sperience could not be
OLYMPUS MEDIC 2951 Ishikawa				Literature	-		time. A supplemental itional and significant
192-8507, Jap			, 10		information become		
				✓ Health Professional ✓ User Facility	Please cross-refer	rence the follo	owing reports for the
4. Date Received by Manufacturer (mm/c	ddiyyyy)	5. (A)NDA #		Company	other eleven cases 2951238-2014-00212		-
05/02/2		IND #		Representative	2951238-2014-00219	, 2951238-2014	4-00220,
6. If IND, Give Protoco	*	STN#		Other:	2951238-2014-00221 2951238-2014-00223		-
		PMAV			2951238-2014-00225		
7. Type of Report (Check all that apply)	,	510(k) #					
☐ 5-day (7) 30-da		Product	Yes				
☐ 7-day ☐ Perio ☐ 10-day ☑ Initia		Pre-1938	Yês				
	w-up #	OTC Product	Yes 🗌				
9. Manufacturer Report	rt Number	8. Adverse Ev	ent Term(s)				
2951238-2014-0	0174						
minutes per response, in sources, gathering and r	ncluding the tir maintaining the . Send comme	me for reviewing e data needed, a mis regarding thi	instructions, and completing is burden est	ng and reviewing the imate or any other aspect of	Department of Health and Hun Food and Drug Administration Office of Chief Information Offi 1350 Piccard Drive, 420A Rockville, MD 20850 Please DO NOT RETURN this	icer	OMB Statement: "An agency may not conduct or sponsor, and a parson is not required to respond to, a collection of information unless it displays a currently valid OMB control number."



February 13, 2015

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is a supplemental report for a previously reported 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,



Copies:

U.S. Department of Health and Human	Services
Food and Drug Administration	

of Event:

or

Date

of Birth:

and/or

(mm/dd/yyyy)

Required Intervention to Prevent Permanent Impairment/Damage (Devices)

2. Outcomes Attributed to Adverse Event

Hospitalization - initial or prolonged

6. Relevant Tests/Laboratory Data, Including Dates

**B. ADVERSE EVENT OR PRODUCT PROBLEM** 

## **MEDWATCH**

FORM FDA 3500A (2/13) A. PATIENT INFORMATION

1. Patient Identifier 2. Age at Time

In confidence

1. 🛄 Adverse Event

(Check all that apply)

Life-threatening

3. Date of Event (mm/dd/yyyy)

5. Describe Event or Problem

Death:

PLEASE TYPE OR USE BLACK INK

For use by user-facilities,
importers, distributors and manufacture
for MANDATORY reporting

Page 1 of ²

lb

kgs

4. Weight

or

3. Sex

Product Problem (e.g., defects/malfunctions)

Disability or Permanent Damage

Congenital Anomaly/Birth Defect

4. Date of This Report (mm/dd/yyyy)

Other Serious (Important Medical Events)

Female

Male

	Form	n Approved: (	UMB No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse.						
r-facilities, and manufact	urers	951238-	2015-00001						
RY reporting	UF/importer Re	UF/Importer Report #							
2									
C, SUSPECT	PRODUCT(S)		FDA Use Only						
1. Name (Give labe	eled strength & mfr/labeler)								
#1									
#2									
2. Dose, Frequenc	cy & Route Used	3. Therap	by Dates (If unknown, give duration) (or best estimate)						
#1		#1	( and countale)						
#2		#2							
4. Diagnosis for L	Ise (Indication)		5. Event Abated After Use						
#1			Stopped or Dose Reduced? #1 Yes No Doesn't						
#2			Apply						
6. Lot#	7. Exp. Date		#2 Yes No Apply						
#1	#1		8. Event Reappeared After Reintroduction?						
#2	#2		#1 Yes No Doesn't						
9. NDC# or Uniqu	e ID		#2 Yes No Doesn't Apply						
10. Concomitant I	Medical Products and The	erapy Dates	s (Exclude treatment of event)						
			(Continue on page 3)						
D. SUSPECT	MEDICAL DEVICE		(Continue on page 3)						
1. Brand Name									
2. Common Devi	ce Name		2b. Procode						
3. Manufacturer I	Name, City and State								

4. Model #	Lot #		5. Operator of Devic
Catalog #	Expiration	Date (mm/dd/yyyy)	Health Professio
Serial #	Unique Ide	əntifier (UDI) #	Other:
6. If implanted, Give Da 8. is this a Single-use D			ive Date <i>(mm/dd/yyyy)</i> ed on a Patient?
9. If Yes to Item No. 8, 1	Enter Name and Ad	dress of Reprocess	Dr
10. Device Available for	Evaluation? (Do n	at condito EDA)	

Returned to Manufacturer on:

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

(Continue on page 3)

(Continue on page 3)

Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

1. Name and Address

E. INITIAL REPORTER

No No

🖌 Yes

Phone # Email Address Initial Reporter Also Sent Report to FDA 2. Health Professional? 3. Occupation Yes No Yes No Unk.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. 01/29/2015

(mm/dd/yyyy)

(Continue on page 3)

MEDW	ÄTC	H					FDA USE ONLY
FORM FDA 3500				Page 2	of 2		
F. FOR USE BY	• •	• •		-			
1. Check One				Report Number	H. DEVICE MANUE		
User Facility	[] Imp	1		cohoir irrinnet	1. Type of Reportable Eve	nt	2. If Follow-up, What Type?
3. User Facility or Imp	·				Death		
• • •					Serious Injury		Additional Information
					Malfunction		Response to FDA Request
							Device Evaluation
					3. Device Evaluated by M	anufacturer?	4. Device Manufacture Date (mm/yyyy)
	····				Not Returned to M	anufacturer	(1111033333)
4. Contact Person			5. Phone N	umber	🖌 Yes 🗌 Evaluat	ion Summary Attached	
					No (Attach page to	explain why not) or	5. Labeled for Single Use?
<ol> <li>Date User Facility o Importer Became</li> </ol>		7. Type of Repo	rt	8. Date of This Report (mm/dd/yyyy)	provide code:		Yes No
Aware of Event (mn	n/dd/yyyy)	🔲 Initial		(		· ·	
		Follow-up #			6. Event Problem and Eve	luation Codes (Refer to	coding manual)
9. Approximate	10. Event	Problem Codes (	Refer to codi	ing manual)	Patient		
Age of Device	Patient	,	ſ <u></u>	·	Code		
	Code	•	-		Code		-
	Device		_			10	
44. Dene # 0	Code				Method	10 - 26	- 37 - 38
11. Report Sent to FD/	47	12. Location W			Results .	3218 - 180	
Yes ( <i>mm/dd</i>	Magad		31	Outpatient Diagnostic Facility			
No (minut		Home		Ambulatory	Conclusions	63 - 19	
13. Report Sent to Mar	nufacturer?		3 Home Ient Treatme	Surgical Facility	7. If Remedial Action Initi	ated, Check Type	8. Usage of Device
Yes		Facility		ni (	Recall	Notification	thitial Use of Device
☐ No (mm/dd	<i>~yyyy)</i>	Other:			Repair	Inspection	Reuse
14. Manufacturer Nam	olAddropp			(Specify)	Replace	Patient Monitoring	Unknown
17. Manufacturer Hailt	0/AUU1055				Relabeling		9. If action reported to FDA under 21 USC 360i(f), list correction/
						³ Adjustment	21 USC 360(f), list correction/ removal reporting number:
					Other:		
					10. 📝 Additional Manuf	acturer Narrative	and / or 11. Corrected Data
G. ALL MANUFA	CTUREF	RS		·····	This supplementa	l report is to	provide the laboratory
1. Contact Office (and	Manufactu	ring Site for Dev	ices)	2. Phone Number	results, and dev	ice evaluation	results.
Name							
Address			······································	3. Report Source	Based on the mic	robiological te	sting conducted by an tested positive for
144/055				(Check all that apply)	Microbacterium 1		
				Foreign	considered clini	cally significa	int and is often an
				Study			anism was recovered from
				Literature	the forceps elev	ator recess.	
Email Address	· /,			Health Professional	The device was E	TO sterilized h	by the off-site laboratory
				User Facility	before returning	to Olympus. A	boroscope was used to
<ol> <li>Date Received by Manufacturer (mm/d)</li> </ol>	ld/yyyy)	5.		Company	examine the inte	rnal instrument	channels and found no pection was performed on
01/23/20	015	(A)NDA #		Representative	the forceps elev	ator and found	no foreign material
6. If IND, Give Protoco		IND #		Distributor	inside. The devi	ce passed leak	test. There were minor
		BLA#		Other:	damages noted on	the device, ho	wever, this would not
		PMA/			likely cause the serviced and ret		omenon. The device was
<ol> <li>Type of Report (Check all that apply)</li> </ol>		510(k) #		-	Serviced and ret	arnea to the as	set factility.
[ 5-day [ √ 30-da		Combination Product	Yes				
7-day Perio	•						
10-day 🛄 Initial	I	Pre-1938	Yes				
🔲 15-day 📝 Follo	w-up # _ 2	OTC Product	Yes				
9. Manufacturer Report	rt Number	8. Adverse Ev	/ent Term(s)	)			
2951238-2015-0	0001						
					1		
This section applie	s only to re	quirements of the	te Paperwoi	k Reduction Act of 1995.	Department of Health and I		OMB Statement: "An agency may not
minutes per response, in	cluding the	time for reviewing	instructions	en estimated to average 66 , searching existing data	Food and Drug Administrat Office of Chief Information	Officer	conduct or sponsor, and a person is not required to respond to a collection of
sources, gathering and n of information. Send corr	naintainina t	he data needed.	and completi	no and reviewing the collection	Paperwork Reduction Act ( PRAStaff@fda.hhs.gov	PRA) Staff	information unless it displays a currently valid OMB control number."
collection of information,	including su	aggestions for red	ucing this bu	any other aspect of this irden to:	Please DO NOT RETURN	this form to the above	PRA Staff email address.

OCA_0001057

## Massachusetts General Hospital, Boston, Massachusetts

U.S. Department of Health and Hum: Food and Drug Administration	· · · · · · · · · · · · · · · · · · ·	For use by	user-façilitie	Š,	Nill Repor	8			1000 00 102010
MEDWATCH	import	ers, distribu or MANDA	tors and mar TORY repor	ulacturers ting	UF/Import	er Report # 251		2014-0000	
#V####################################		Page	1 of ³						
A FAULENT INEORIMATION 1. Patient Identifier 2. Age at Tane of Event: UNK sr	3. Sex	4. Weight	1. Name (C 81	issee site	elliertSjä engit & minted	eler)			FDA Use Ordj
	INK 🗌 Male	UNK kg	#2 2. Dose, Fi	squency & R	oute tierd	3. There	w Oates /	นี้ เหารรรณหรร. เว	;/ve duration)
BUADVERSE EVENDOR PRODUC	AN RECISION		#1			370377/20 #1	for best e	nstimata)	, so building
1. Z Adverse Event and/or Pro 2. Outcomes Attributed to Adverse Event	suct Problem (e.g., delects/m	sifunctions)	#2			***			~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
(Check sli that apply)			1	ls for Use (in:	fication)			Abated Afte	
Desth:	Disability or Permanent I	Damage	#1					ed or Dase f (es 门 No	Reduced? ;```; Doess'
	Congenital Anomaly/Birt		#2					~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	····· Apply
Hospitalization - initial or prolonged     Required Intervention to Prevent Permi	Other Serious (Importan		6. Lot #		7. Exp. Dat	5	#2 🛄 Y	(es () No	C Doesn' Apply
3. Date of Event (mm/dd/yyyy)	4. Date of This Report (mm		<b>#1</b>					Reappeared aduction7	Anor
2014	11/17/20	14	#2		#2		#1 🗋 1	res 🔘 No	Doesn' Apply
5. Describs Event or Problem On 11/17/2014, PENTAX Medica	l received a repar	t from	9. NDC# 9/	Unique ID			#2 1 1	/es ()) No	····· Doesn'
Patient Inform Unit at Nessachusetts Genera	ation	10	10. Concor	nilani Medica	Products and	Therspy Dates			فينيا Apply eventi
Duodenoscope Model ED-3490TK increased incidence in post- coli bacteremia. The Duoden with a significantly higher The Duodenoscope was raturne 12/01/2014 and is currently	procedure drug-res oscope was also as: proportion of infe d to SENTAK Medica.	istant E. sociated ctions.	Bassisiss 1. Srand N		ICAL DEVIC		(C	Continue or	1 page 3)
In order to receive addition	al information reg.	arding the		n Device Nam	*			••••••	****************
event, FENTAX Medical contac email on 12/15/2014.	ted the initial rep	porter via	3 Manufac	uodenosoo himor Náms, G porstilon apan	~~~~~		FDT		8
			A Stodel #	·····	Lot#			5. Operator	r of Davica
			Catalog	~~~~~	N/A	tion Date (mm/			Professional
			N/A	<i>7</i>	Carbon e	N/A	360 9 8 9 8 9		seriPatient
			Seriel # A:10428	·	Uniqu N/A	a klentifler (UDi	\$#	Cither;	
			§ §		e (mm/dd/yyyy)	7. If Expl	anted, Git	j va Data (mm	<i></i>
8. Relevant Tasta/Laboratory Data, including		on page 3)	- <u>8/A</u>			N/A			
87A			💭 Yes	Z Ko		Reprocessed a Address of Rej			***
									~~~~~~
			(7) Yes	Averages and the contract of t		o not send to FC to Manufactures	•	12-01-2	
								(mm/dd/y)	
 Other Relevant History, including Preaxis race, pregnancy, amoking and elcohol use, I N / N 		on page 3) , allargies,	N/A	7785-86565, DB 8822365-86	9 P 10000518 8110	Therepy Dates		ceement or Continue or	
			t <u>Namea</u> Pati Massach SS Frui		ation meral Bos Bulfinch	3~331			
	(Continue	on page 3)	DNE			Emsil Address Patient II	nforma	tion	
Submission of a report does not con personnel, user facility, importer, dis	stitute an somission th	at medical	Z. Heslih P	rofessional?	3. Occupation	1	4.1	initial Report Report to FD	ter Also Son A
caused or contributed to the event.	NO CONSIGNER STREETENESSERVER	w, 928.09699995695	🔀 Yes	C) No	Norse				No 🖉 Unk

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FORM FDA 3500			Page	*****		
000000000000000000000000000000000000000	USERIFA					
1. Check One User Facility	E di taman	2. UF/importer F		1. Type of Reportable Ev	ant	2. If Follow-up, What Type?
	Social N					Connection
3. User Facility or imp FENTAX Medical		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		Sarious Injury		Additional Information
3 Paragon Driv				Nation		Response to FDA Request
Mostvals, NJ O	7645			5 		Device Evaluation
				3. Device Evaluated by N	· ·	4. Device Manufacture Date (mm/yyyy)
Conton Desce		25 Phase 0		Not Returned to N		04/2012
4. Contact Person		S. Phone N	792281	{	Non Summary Attaction	5. Labaled for Single Use?
6. Date User Facility o	ir 17	. Type of Report	8. Date of This Report	provide code:	a exterena muà udi) de	-
Importer Became Aware of Event (mn		[7] Initial	(mm/dd/yyyy)			🗍 Yes 😨 No
11/17/201	5	Follow-up #	12/15/2014	6. Event Problem and Ev	alustion Codes (Refer it	coding menuelj
9. Approximate	l.	rublem Codes (Refer to codi		Patient	1735 -	
Age of Device				Code Device		
» years	Code	1735 -		Code	3190 -	·
te Maria	Cevice C	3190 ~	~	Mathod	7BD ~]-[]
11. Report Sent to FDA		12. Location Where Event	Occurred	Results	3233 ~	
@ Yes 12/15/	/2014	Mospital	Cuspatient Dispussic Facility			and harmonical harmonical
No (nem/do	4797907	Home	[T] Ambulatory	Candusians	11 ~	
13. Report Sent to Mar	nuisciurer?	Nursing Home Outpatient Treatment	Surgical Facility	7. If Remedial Action Init	isted, Chack Type	A. Usage of Device
Yes 12/15/		Facility	n	Recall (Notification	initial Use of Device
No pumbos	73259	Cther:	(Specify)	🗌 Repair 👔) Inspection	Reuse
14. Manufacturer Nam	e/Addrass		10,000.00	Replace 💭] Patient Monitoring	Unknown
Hoya Corporati		4 C Z I		Relabeling (Modification/ Adjustment	9. If solion reported to FDA under 21 USC 36041, list correction/
PENTAN Life Ca. 2-7-5 Naka-Paj				Other	^ ·	removal reporting number: N/A
Tokyo, Japan 1		•				
				10. Additional Manuf	sciurs: Narralivs	and / or 11. Corrected Data
				»/»		tt
1. Contact Offica (and	Manufacturi	ing Site for Devices)	2. Phone Humber			
Name			see F.S			
Address			3. Report Source (Check of thet apply)			
			C Foreign			
Contact office			Study			
Manufacturing :	site - S	ee F.14 apove	C Literature			
Empli Address	•••••		. Consumer			
			Health Professional			
4. Date Received by Manufacturer (mm/d	(givervo)	<u>ş</u> ,	User Facility			
11/17/2		(A)NDA #	Company Representativa			
6. If IND, Give Protoco		**D #	Distributor			
N/A		BLA #	(Cather:			
7. Type of Report		PMA/ 510(k) # K092710				
(Cinuck all that apply)		Combination				
□ S-day ☑ 30-da		Product Ves				
Perio		Prø-1938 🗍 Yes				
8 www	, ₩~₩29.#	OTC Product Ves				
3. Menufacturer Repor		6. Adverse Event Term(s)	£			
N/A		N/A				
This seation ours	and shakes a second	S	Conduction And reasons	Reperiment of Lizzib and L	(18985 Chajano	Alth Statement 24. Anna
The public reporting burn	sen for this co	uirements of the Paperwori Section of information has be	en estimated to average 66	Department of Health and H Food and Drug Administration	on.	OMB Statement: "An agency may not conduct or sponsor, and a person is not
		me for reviewing instructions, a data needed, and completin		Office of Chief Information (Paperwork Reduction Act (F		required to respond to, a connection of information unless it displays a currently
of information. Send com	nments regar	ding this burden externate or a gestions for reducing this bur	ny other aspect of this	° PRASIMBIUS.hhs.gov Piezze DO NOT RETURN (ihis form to the sbove F	valid OMB control number."
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(CONTINUA NON PAGE) For use by user-facilities, importers, distributors, and manufacturers

for MANDATORY reporting Page 3 of 3

MedWatch

FORM FDA 3508A (2/13) (continued)

nuad)

	B.S. Describe Event or Problem (continued)
	N/A
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Back to Hom B.5	
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	B.6. Reisvant TestsA.aboratory Data, including Datas (continued)
	N/A.
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Back to Høm B.S	
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	B.7. Other Relevant History, Including Preexisting Medical Conditions (a.g., allergies, race, pregnancy, smoking and sicohol use, hepotic/enal dysfunction, etc.) (continued)
	N/A
2	
Back to Nem B.7	
3888	
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C. 18	
ġ	Concomitant Hedical Products and Therapy Dates (Exclude treatment of eveni) (For continuation of C.10 and/or D.11; please distinguish)
200	N/A
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38 23	
В. С	
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8	
Back to item D.11 Back to item	
а Жа	Other Remarka
	Patient Code 1735 - Bacterial infection. Device Code 3190 - No Information. Method Code - To be
	Determined. Results Code 3233 - Results Pending Completion of Svaluation. Conclusions Code 11 -
	Conclusion not yet available, Evaluation in Progress.

U.S.	Department	of Haalth	and Hu	iman Services	5
Faac	i and Drug Ac	iministratik	m		

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For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

UFAmparter Report #	2518897-2015-00009

FORM FDA 350	0A (2/13)			Page	1 of <u>3</u>
1. Patient Identifier	elitionApplein 2. Age at Time of Event: Dr Date	uk sing	3. Sex	4. Weight UNK to ar	
in conlidence	of Binth:	UNK	Male Male	UNK kg	15 2. 2. Dose, Frequency
B. ADVERSE E	VENT OR PRO	DID(GIT PIR(D)3103	М		
1. 🕢 Adverse Even	and/or 🔀	Product Problem (a.g., dalacts/meth	unctions)	#1
2. Outcomes Attribut (Check of that appl		65		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	#2
Deatro		Disability	or Permanent Da	mage	4. Diagnosis for Use
Life-threatenin	(mm/30/yyy) 9	Congenity	# Anomsly/Birth C	Xefect	#1
Hospitalization	- - initial or protonges	-	ious (important M		s) #2
Required Inter	vention to Prevent P	emanent Impairmer	WDamage (Devic	8 5}	6 Lots
3. Oats of Event (mr	viddlyyyy)	4. Data of This	Report (mm/dd	¥yyyy)	- #1
	2014				#2
5. Describe Event or FENTAX Medica.		the Initial F	eporter vi	3 (00-11)	S: NDC# or Unique I
on 01/05/2018 from the facil tested positiv resistant E.co Video Duodenos Strain typeš !	and 01/20/2 lity on 01/2 ve for a sim oli post-ERC scope Model 1 5A-H are rel.	015. Respons 3/2015 indica gle strain ty F procedure p ED-3490TK/Sea	es were re ting > pat pe of ceft erformed w ial All32 Sther. Pat	veived lents riaxone- ith 8. ient	10. Concomitant Ste
mee the meaning paties 72 hours. Th e part of the he	nt had (+) b. facility pro	lood culture stocol for fr	post-ERCP fections t	within hat arg	998-381-3212(ener/) 9. Srand Name
pacteremias, : provider are :	is that the o	department le	adership a	nd the	2: Common Device I
identified an: analysis) is (d a review o. completed. T	f the infecti se group of p	on (root c atients un	ause dergoing	3. Manufacturer Nan
ERCP was being biliary diseas specific signs	ses: it would s and symptom	d be difficul na other than	t to deter fever/chi	aine lls and	4. Nodel #
walsine that) batteremias. appropriate as	Patient was !	treated for t	acteremias	with	Catalog #
further scree:	ning as the s	earker for th	is outbrea		Guidary
investigation	was a (+) b.	1000 culture	tor (Continue or	1 0208 31	6. H Implanted, Give
5. Relevant Yests/Let	•		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		- l & is this a Single-us
Strain type as electrophores;		by pulsed-fi	eld		
Fime of lst(*)		kuinhin 99 ha	1178 AF A	an adapt ments	9. If Yes to Item No. i
Date of Scope		formation	ara Ar bib;	.⇔unre)	
Site of(+)cul?	ture - Blood				18. Device Available
			(Continue on	page 3)	11. Concomitant Mag
7. Other Relevant His rece, pregnancy, sm	tory, including Pre toking and alcohol u	ezisting Medical Co se, hepstichenei dys	náitions (e.g., si		~
					1. Name and Address
					Phone S

FOA Use Only ;(e)e)e(e)(;;) d strangilli & minilabelar) & Route Used Therapy Dates (If unknown, give duration) from/to (or best estimate) 81 \$2 (Indication) 5. Event Abeted Atter Use Stopped or Dose Reduced? Stoppes or Joss Desart \$1 Yes No Desart Doesn' Apply #2 🗌 Yes 🔲 No 7. Exp. Oste Event Responsed After Reinfroduction? \$1 #2 Cossn't Apply #1 🗌 Yes 🔲 No Doesn' #2 🗌 Yes 📋 No Apply Apply dical Products and Tharapy Dates (Exclude treatment of event) (Continue on page 3) EDICAL DEVICE vame 2b. Procode ns, City and State 6.003 5. Operator of Device 门 Health Protessional Explication Date (mm/dd/yyy) Lay User/Palient Cther: Unique Idontiñar (UDI) # Date (mm/dd/yyyy) 7. If Explanted, Give Date (mm/dd/yyyy) e Device that was Reprocessed and Reused on a Patient? 8, Enter Name and Address of Reprocessor for Evaluation? (Co not send to FDA) Returned to Manufacturer on: (mm/dd/yyyy) lical Products and Therapy Datas (Exclude treatment of event) (Continue on page 3))RTER

Email Address

2. Health Professional? 3. Occupation

Yes No

(Continue on page 3) Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

4. Initial Reporter Also Sont Report to FDA

Yes No Unk

FORM FDA 3500A			(*)	Page :	******		*
1. Check One	~~~~	2. U	*******	Raport Number	1. Type of Reportable Ex		2. If Follow-up, What Type?
User Facility or Import	impori Inf Name/A		9997~20	15~00009	Desth Desth Desth Desth Desth Desth Desthese by the	fanufacturee?	Correction Connection
4. Contact Person	·····		5. Profe N	unper	Not Returned to A	áanulacturer alivn Summary Allached	<i>,</i>
6. Data User Facility or Importer Bacama Awars of Event <i>(mm/c</i> c	annni [Type of Repor	τ	8. Data of This Report (mm/dd/yryy) 06/23/2015	No (Altach page) provide code: 6. Event Problem and Ev		5. Labelad for Single Use?
8. Approzimate 10		-) · calor do *	Refer (c coci	l ng manual)	Potent Corie	2735 -	~
୍ ପ ଅନ୍ୟ ସ	ationt cde evice cde	1735 -	·	~	Caller Device Cade Method]-[]
11. Report Sent to FDA? [7] Yes	015 999	12. Location W ()) Haspita ()) Hame ()) Nursing	ł	Occurred Outpatient Diagnostic Facility Ambulatory Surgical Facility	Results Consideres	- -	
Yes 05/23/20 Mo Mo Mo Manufacturar Nama/A	015 yy)	"" Facility	sni Treatmer	13	7. If Remedial Action Init Recall Repair Replace	lated, Chack Type] Notification] Inspection] Patient Monitoring	8. Usage of Device I Initial Use of Device Reuse Unknown
Central Bio MADUBISTICS 1. Contect Office (and Ma Name		ıç Sita for Devi	ces)	2_Phone Rumber	18. []] Additional Wenuf	isciuror Narrativa	and / or 11. []] Corrected Date
Adistress Email Address				Report Source (Check of the apply) Foreign Study Utersture Consumer Meatth Professional			
Data Received by Wanulacturer (minidal) 01/23/2011 01/23/2011 B. If IND, Give Protocol 8	2222)	5. (ANDA # IND # BLA #		User Facility Company Reprosentative Distributor			
7. Type of Report (Check all that spply) [] 5-day [] 30-day [] 7-day [] Periodic		PitAu 510(k) # Combination Product Pre-1938	Yes				
19-day [2] Initial 19-day [] Folice-u 9. Manufacturar Report M		OTO Product 8. Adverse Ev	☐ Y∞ mi Term(s)				
The public reporting burden minutes per response, inclus	for this cold ding the time Maining the wis regardle	sction of inform: 8 for reviewing i data needed, a	ation has been nativations, so completin stimate or ar	searching existing data 3 and reviewing the collection	Cepartment of Health and H Food and Drug Administratis Office of Chief Information S Paperwork Reduction Act (F PRAStaffords.ths.gov Presse OG NOT RETURN 1	on Micer YRA) Slaff	OKE Statement: "An agency may not conduct or sponsor, and a person is no required to respond to, a collection of information unless it displays a current wold OMS control number."

averiga to The partic reporting burden to the coection of information has been sourced to average 5% minutes per response, including the time for reviewing instructions, searching existing data Sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other espect of this collection of information. Including suggestions for reducing this burden to:

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Paperwork Reduction Act (PRA) Staff Information unless it dis PRAStaffgittà tha gov valid OMB control numb Plesse DG NOT RETURN this form to the above PRA Staff email address.

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(CONTINUATION PAGE) For use by user-facilities, importers, distributors, and manufacturers for MANDATORY reporting

MedWatch

FORM FDA 3500A (2/13) (continued)

Page 3 of 3

8.5. Describe Event or Problem (continued) ceftriaxone-resistant E.coli: all(+)blood cultures are reviewed daily by infection preventionists. 30 day Initial MDR 2518897-2014-00012 was filed on 12/15/2014 which included Initial information regarding this event. Follow up#1 MDR 2518897~2014~00012 includes additional information received from the Initial Reporter on 01/23/2015 and 06/11/2015 on patient ID Initial MCR 2518697-2015-00009 includes additional information received from the Initial Reporter on ø 01/23/2015 in regards to patient ID 11033 Initial MDR 2518697-2015-00010 includes additional information received from the Initial Reporter on 01/23/2015 and 06/11/2015 on patient ID 2 Initial MDR 2518897-2015-00011 includes additional information received from the Initial Reporter on 01/23/2015 and 06/11/2015 on patient ID Initial MDR 2518897-2015-00012 includes additional information received from the Initial Reporter on 01/23/2015 in regards to patient ID I Initial MDR 2518897-2015-00013 includes additional information received from the Initial Reporter on 01/23/2015 in regards to patient ID Initial MDR 2518397-2015-00014 includes additional information received from the Initial Reporter on 01/23/2015 and 06/11/2015 on patient ID S.S. Relevant Tests/Laboratory Data, including Datas (continued) Back to Rem B.S B.7. Other Relevant History, including Pressisting Medical Conditions (e.g. allergies, race, pregnency, smoking and alcohol use, hepaticitenal dysfunction, etc.) (continued) Back to Nom B.7 Back to Rem D.11 Back to Rem C.10 Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C 10 and/or D.11; please distinguish) Other Remarks Patient Code 1735 - Sacterial infection.

Form	Approved:	OMB	No.	0910-0291	I, Expires:	6/30/2015
			6	CONCE OF	tatamant r	

	J.S. Department of Health and Human Services For use by us Food and Drug Administration	er-façilities,	Mir Report #		ee OMB statement on reverse.
	Food and Drug Administration importers, distributor for MANDATC	RY reporting	UF/Importer Re	pon# 2518897-	2015-00018
	FORM FDA 3500A (2/13)	of 3			FDA Use Only
	A. PATIENT INFORMATION 1. Patient identifier 2. Age at Time of Event: 4. Weight br	C. SUSPECT PROD 1. Name (Give labeled stree #1			
	Date Or Male	#2			
	In confidence of Birth: L Mars kgs B. ADVERSE EVENT OR PRODUCT PROBLEM	2 Dose, Frequency & Ro	ute Used	3. Therapy Dates from/lo (or best	(If unknown, give duration) estimate)
	1. Adverse Event and/or Product Problem (e.g., defects/malfunctions)	#1		#1	
	2. Outcomes Attributed to Adverse Event	#2	1. S. 1998	#2	
	(Check all that apply) Death (mm/dd/yyyy) Disability or Permanent Damage	4 Diagnosis for Use (Ind. #1	ication)	Stop	It Abated After Use ped or Dose Reduced? Yes No Doesn't
	Life-threatening Congenital Anomaly/Birth Defect	#2			- Appiy
	Hospitalization - Initial or prolonged Other Serious (Important Medical Events) Image: The serious of the series of the	6. Lot #	7. Exp. Date		Yes No Apply
	3. Date of Event (mm/dd/vyyy) 4. Date of This Report (mm/dd/vyyy)		#1		t Reappeared After troduction?
	Patient Information 01/23/2015	#2	#2	#1. 🔲	Yes No Doesn't Apply
	5. Describe Event or Problem PENTAX Medical received a report on 01/23/2015	9, NDC# or Unique ID	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	#2	Yes No Doesn't Apply
	indicating 1 patient tested positive for a single strain	10. Concomitant Medical	Products and The	rapy Dates (Exclud	
INK	type of ceftriaxone-resistant E. coli post-ERCP procedure. No information on the Medical Device used during the ERCP procedure was received at the time of this report. Patient met the case definition of "Delayed bacteremia post-ERCP" meaning patient had (+) blood culture post-ERCP after 72 hours but within 30				Continue on page 3)
LACK	days post-procedure. The facility protocol for infections that are part of the hospital surveillance	D. SUSPECT MEDI	CAL DEVICE		
E BL	plan, which includes bacteremias, is that the department leadership and the provider are notified of the	2. Common Device Name) ·····	2b.	Procode
OR US	infection; any trends identified and a review of the infection (root cause analysis) is completed. The facility also indicated that patients undergoing ERCP	3. Manufacturer Name, C	ity and State		
TYPE	are being treated for a range of pancreatic and biliary diseases; it would be difficult to determine specific signs and symptoms other than fever/chills and malaise	4. Model #	Lot #	1	5. Operator of Device
EASI	that would be related to the post-procedure bacteremias. Patient was treated for bacteremias with appropriate antibiotics. Patient was not recalled for further	Catalog #	Expiration Unique Ide	Lay User/Patient	
Dd	screening as the marker for this outbreak investigation	South the	Gingerio	anner (obij r	
	was a (+) blood culture for ceftriaxone-resistant (Continue on page 3)	6. If Implanted, Give Date	a (mm/dd/yyyy)	7, If Explanted, C	ilve Date (mm/dd/yyyy)
	6. Relavant Tasts/Laboratory Data, Including Datas Strain type as determined by pulsed-field electrophoresis - 8	8. is this a Single-use Da			
	Time of lst(+)culture - Delayed(>72 hours but <30 days)	9. If Yes to Item No. 8, E	nter Name and Add	iress of Reprocess	10
	Date of Scope Use - Patient Information	10. Device Available for	Evaluation? (0o po	I sand to EDA)	
	Site of (+) culture - Blood	Yes No	Returned to N		(mm/dd/yyyy)
	(Continue on page 3)	11. Concomitant Medica	Products and The	rapy Dates (Exclu	de treatment of event)
	 Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) 				(Continue on page 3)
		E. INITIAL REPOR 1. Name and Address Patient Inform MGH Gastroentero 55 Fruit Street, Boston, MA 02114	ation blogy Associa Blake 4	ates	
	(Continue on page 3)	Phone # Patient Information	l Fm	Patient Inf	ormation
	Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.	2. Health Professional?			Initial Reporter Also Sent Report to FDA Yes V No Unk.
	amaan al palifikardo ja fils sagilt		J		

F. FOR USE BY USER FA	CILITY/IMPORTER (Devices Only)	H. DEVICE MANUFA	CTURERS ONLY	
1. Check One		Report Number	1. Type of Reportable Even	•	2. If Follow-up, What Type?
User Facility 📝 Impo	and a second	015-00018	Death		Correction
 User Facility or Importer Name/ PENTAX Medical 	Address		Serious Injury		Additional Information
B Paragon Drive			Malfunction	san ing pangakan Managarta	Response to FDA Reque
Montvale, NJ 07645					Device Evaluation
			3. Device Evaluated by Mar	ufacturer?	4. Device Manufacture Date (mm/yyyy)
	1.001.001.001.001.001.001.001.001.001.0		Not Returned to Mar	ufacturer	fumerki ki
4. Contact Person	5. Phone		Yes C Evaluatio	n Summary Attached	
Anastasia Vlami#		1-2300- x2066	No (Attach page to e provide code:	explain why not) or	5. Labeled for Single Use?
Importer Became	7. Type of Report	8. Date of This Report (mm/dd/yyyy)			Yes No No No
Aware of Event (mm/dd/yyyy)	✓ Initial	07/02/2015	6. Event Problem and Evalu	untion Pades (Deles is	
	Follow-up #	••	Patient		
9. Approximate 10. Event F Age of Device	Problem Codes (Refer to co	ding manual)	Code	1735 -	
Patient	1735		Device	3190 -	
Code Device					and have been a featured from the second feature of the second fea
Code	3190 - 1 -		Method	-	
11. Report Sent to FDA?	12. Location Where Even	t Occurred	Results		
Yes 07/02/2015	Hospital	Outpatient Diagnostic Facility		L	
No (mm/dd/yyyy)	Home	Ambulatory	Conclusions		
13. Report Sent to Manufacturer?	Nursing Home	Surgical Facility	7. If Remedial Action Initiat	ed, Check Type	8. Usage of Device
Ves 07/02/2015	Outpatient Treatm Facility	ent Sassas a substantia da subs	Recall	Notification	Initial Use of Device
	Other	(Dame 24)	Repair	Inspection	Reuse
		(Specify)	Replace	Patient Monitoring	Unknown
10 Manufacturar ManalAddraea					F1 68
14. Manufacturer Name/Address Hoya Corporation				erwannowshare j	 If action reported to FDA under 21 USC 360/0, list correction/
Hoya Corporation PENTAX Life Care Tokyc				Modification/ Adjustment	 If action reported to FDA under 21 USC 360i(f), list correction/ removal reporting number;
Hoya Corporation PENTAX Life Care Tokyc 2-7-5 Naka-Psjao, Shir				erwannowshare j	21 USC 360i(f), list correction/
Hoya Corporation PENTAX Life Care Tokyc			Other	Adjustment	21 USC 360(f), list correction/ removal reporting number:
Hoya Corporation PENTAX Life Care Tokyo 2-7-5 Naka-Psjao, Shir Tokyo, Japan 161-8525	1juku-ku			Adjustment	21 USC 360i(f), list correction/
Hoya Corporation PENTAX Life Care Tokyo 2-7-5 Naka-Psjao, Shir Tokyo, Japan 161-8525 G.ALL MANUFACTURER	njuku-ku		Other	Adjustment	21 USC 360(f), list correction/ removal reporting number:
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Hoya Corporation PENTAX Life Care Tokyo 2-7-5 Naka-Psjao, Shir Tokyo, Japan 161-8525 G. ALL MANUFACTURER 1. Contact Office (and Manufactur Name Address Contact office - See E Manufacturing site - S Email Address Email Address 4. Date Received by Manufacturer (mm/dd/yyyy) 01/23/2015 6. If IND, Give Protocol # 7. Type of Report (Check all that apply) 5-day Periodic 10-day V Initial 15-day Follow-up #	S ring Site for Devices) 7. 3 above see F.14 above 5. (A)NDA # IND # BLA # PMA/ 510(k) # Combination Product Yes 0TC Product Yes 8. Adverse Event Term(st objection of information has b	see F.5 3. Report Source (Check all litel apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other:	Other	Adjustment	21 USC 360(f), list correction/ removal reporting number:

MEDWATCH

Back to Item B.5

Back to Item B.6

Back to Item B.7

Back to Nem D.11 Back to Nem C.10

Other Remarks

FORM FDA 3500A (2/13) (continued)

(CONTINUATION PAGE) For use by user-facilities, importers, distributors, and manufacturers for MANDATORY reporting Page 3 of 3

B.5. Describe Event or Problem (continued)

E.coli; all(+)blood cultures are reviewed daily by infection preventionists. PENTAX Medical contacted the Initial Reporter via email on 05/05/2015, 05/21/2015, 06/12/2015 and 06/23/2015 to confirm the Medical Device used during the ERCP procedure. Also, the Initial Reporter was contacted via email on 05/21/2015 and 06/23/2015 in regards to current patient status. No information on the Medical Device involved in this event or current patient status information for Patient ID ERCP2 have been received from the facility to date.

8.6.	Relevant	Tests/Laboratory	Data, Includ	ling Dates	(continued)

이번 사람이 많이 많이 있는 것이 같은 것이 같은 것은 것은 것이 같은 것이 많이 많이 있는 것이 같이 없는 것이 없다.

B.7: Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)

Patient Code 1735 - Bacterial infection. Device Code 3190 - No Information.

	2 Providence and a Pilling for the second state of the second sec			5, 260.01	i Marpi GY613, Cirri 	See OMB states	pares: svaurzon: pares: svaurzon: pares: svaurzon:
	U.S. Department of Health and Human Services Food and Drug Administration	For use by u	ser-facilities,	Mr Report #			
		for MANDAT	ors and manufacturers ORY reporting	UF/Importer Re	port # art of	97-2015-000	***
	MedWatch			000000000000000000000000000000000000000	22192	.97~2015~000.	31
	FORM FDA 3500A (2/13)	Page 1	of <u>3</u>				FDA Use Only
	A PATIENT INFORMATION		(*** \$11\$12120118323(8))				ron use uniy
		3. Sez 4. Weight	1. Name (Give labeled strer	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			
	UNE of Event: UNK	Female UNK Ibs	#1				
	Or	or					*******
	in confidence of Birth:	Male UNK kgs	#2				
	E ADVERSE EVENILOR PRODUCT PROBLEM		2 Dose, Frequency & Rou	ne Usod	3. Therapy D from/to (or	latas (Il unknown, ç basi estimata)	jine distation)
	1. 📝 Adverse Event and/or 📝 Product Problem (e.	a defecte in with we time of	#1		#1	-	
	2. Outcomes Attributed to Adverse Event	\$1, 18100127118101010101073y	#2		#2	******************************	~~~~~
	(Check all that apply)		4 Diagnosis for Use (India	stion	£	Event Abated Afte	e Liso
	Death: Disability or	Permanent Damage	\$1	,		Stopped or Dose F	Reduced?
		Anomaly/Birth Defect				🗍 Yes 🛄 No	C Doesn't Apply
	Hospitalization - initial or prolonged (Cither Serio	us (Important Medical Events)	\$2			[m Doesn't
	[7] Required Intervention to Prevent Permanent Impairment/		6. Lot#	7. Exp. Date		Yes No	Apply أسا
	3. Date of Evant_imm/different 4. Date of This I	Report (mm/dd/syys)	#1	#1		Evant Raappeared Reintroduction?	Attos
		37/20/2015	#2	#2	ł	TYes The	Doesn't
	5. Describe Event or Problem		9 NOC# or Unique ID			·····	Apply
	PENTAX Medical was made aware of an eve				\$2	□Yes □No	Deesn't Apply
	stating "Post ERCP Sacteremias with CTX has been associated with 3 patients sin		10. Concomitant Medical P	roducts and Ther	spy Dates (Ex	clude treatment of	svan()
	Duodenescope involved was received at E						
	07/09/2015 to repair a reported leak an	d is currently on					
XNI	hold pending further evaluation.						
	Good Faith Effort attempts were made vi	a e-mail on				(Continue on	page 3)
ACK	07/23/2015 and 07/30/2015 to the facili	ty to confirm	D. SUSPECT MEDIC	AL DEVICE			
BLA	details of the event, and to obtain a f	scility contact	1. Brand Name PEBTAX				
	to receive information on the 3 patient	.3.	2. Common Davice Name	***********	***************************************	2b. Procode	*****
USE	No information has been received from t	he facility to	Video Duodenoscap			FOT	
ő	date.		3. Manufacturar Name, City HOYA Corporation	y and State			
$\frac{2}{\omega}$			Tokyo, Sapan				
TYPE			4. Model #	Lot#		5. Operator	of Device
			2D-3490TK				Professional
PLEASE			Catalog \$	Expiration I	Date (mm/dd/y	www king	enPatient
ω			Serial #	Blazaria falaz	ulifier (UDI) #	C Other	
Z			8110743	writegore sweet	www.torod.e	tand second	
			6. If implanted, Give Date (mm/dd/yyyy;	7. If Explante	id, Give Date (mm/	60/222
	6. Relevant Tests & aboratory Data, Including Dates	(Continue on page 3)				· · · ·	
			8. is this a Single-use Devi	cs that was Repro	cessed and f	loused on a Patier	nt?
			9. If Yes I No. 8, Ente	ar kinna und Adda	ora of Bacene	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	
				an territoria santar maaaas	ana ni iatina		
			10. Device Available for Ev	sluation? (Do not	send to FDA)		~~~~~~
			Yes No (🕖 Returned to Ma	mutacturer on:	07/09/3	
		(M) (I) (D)	11. Concomitant Medical P	erende in dar market These	Dates 200	(mmVdd/y) In haanse stad	
	***************************************	(Continue on page 3)				addib o ddiffiaid di	arony
	 Other Netwoant History, Including Preexisting Medical Con race, pregnancy, smoking and alcohol use, hepaticitenel dystu 	nction, etc.)					
00000			000000000000000000000000000000000000000			(Continue on	page 3)
			E INITIAL REPORT	3R			
			Identifying Information				
			Massachusetts Gen	ersi Hosnita	s].		
			55 Fruit Street,				
			Soston, MA 02114				
			Phone #) be 191 al	Address	****	
		(Continue on page 3)	Identifying Information	1		Information	
	Submission of a report does not constitute an adm	ission that medical	2. Health Professional? 3	Occupation	00000000	4. Initial Report	ar Also Sent
ş	personnel, user facility, importer, distributor, man caused or contributed to the event.	ufacturar or product	Yes 7 No N	IA		Report to FD.	a i
	manakaranak ana anakeasa casak 655 kut 654 kut 65 kut 65 kut 65 kut		است سند			1 [] **** [~~ <u>~</u>

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1 Import Number 1 Control Contro Control Control <	1. Check One	, r		•	*	1. Type of Reportable	ียงอาส	2. If Follow-up, What Type?
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			8/ACD1955					
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0.7287/2015 Proceeding manualy Age of Decide Proceeding Proceeding Proceeding Proceding	Aware of Event (m	niddlyyyyy)	📝 Initial					
Age of Device 10 Board Problem Cooles (PMOV to Cooleg remound) Processor 1733 Processor 1733 Processor 1733 Processor 12 Location (PMove Event Occurred In Coolegation Franking Processor 12 Location (PMove Event Occurred In Coolegation Franking Processor 12 Location (PMove Event Occurred In Processor Processor 12 Processor Pro	07/28/20.	15		\$	03/11/2015	6. Event Problem and	Evaluation Codes (Refer	to coding manual)
Paper District Processor 27.25		10. Event	1 4995)) ing manuali		1 1735 -	
Code 17.35 =	Age of Device	Patient f	a m n m	1 1			n t i i i	
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Email Address Image: Health Professional Data Received by S. Manufacturer (mm/ddyyyyr) S. Q3/20/2015 RU # IND, Give Protocol # BLA # Distributor Other PI(A/ 510(k) # K092710 Other Frage of Report (Check all that exply) Combination Product Stoky Dotal Product Type of Report (Check all that exply) Combination Product Stoky Periodic Product Tray Periodic Product Yes T-day Polow-up # Its-day Polow-up # Its-day Polow-up # This section applies only to requirements of the Paperwork Reduction Act of 1985. Insides per resportse, including the tame for reviewing instructions, searching asisting dida multies per resportse, including the tame for reviewing instruction, searching asisting dida Department of Health and Huntan Services Food and Crug Administration Office of Cheel Information Act (PA) Staff OMME Statement: "An agoincy may paid constact or spensor, and a person is no required in respond to, a collection of information Act (PRA) Staff	lanufacturing	site -	300 F.14 a	bove				
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	purces, gathering and r	naintaining t	he data needed,	and completiz	g and reviewing the collection	Paperwork Reduction Ac PRAStat@ida.hhs.gov	I (PRA) Staff	

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(CONTINUATION PAGE) For use by user-facilities, importers, distributors, and manufacturers

> for MANDATORY reporting Page 3 of 3



FORM FDA 3500A (2/13) (continued)

8.5. Describe Event or Problem (continued)

Back to item B.5 8.6. Relevant Tests/Laboratory Data, including Dates (continued) Back to Nem B.5 6.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, amoking and alcohol use, hepatic/renal dysfunction, etc.) (continued) Back to flem B.7 Back to Rem D.11 Back to Rem C.10 Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11, please distinguish) Other Remarks Patient Code 1735 - Bacterial Infection Device Code 2379 - Device Issue Method code 10 - Actual Device Evaluated Results code 3233 - Results Pending Completion of Evaluation Conclusions Code 11 - Conclusion Not Yet Available - Evaluation in Progress

New York-Presbyterian/Weill Cornell Medical Center New York City, New York

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June 7, 2013

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,



OCA_0000739

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11 See OMB statement on reverse

	U.S. Department of Health and Human	n Services				C	Mfr Report #		300	OME statem	nent on reverse
	Food and Drug Administration		importers	or use by distribu	tor	ser-facilities, rs and manufacturers	Win Report# 80	010047-20	13-00	0176	
	MEDWATCH					ORY reporting	UF/Importer Rep	port#			
	FORM FDA 3500A (1/09)			Page	1	of ²					
1	A. PATIENT INFORMATION					C. SUSPECT PROD			_		FDA Use Only
	1. Patient Identifier 2. Age at Time		3. Sex	4. Weight		1. Name (Give labeled stre					
	of Event:		J. Jek	4. Weight	1	1	ngar a miniabelely				
	ог		Female	lb	s	#1					
	Date		Male	or		#2					
	In confidence of Birth:			kg	5	2. Dose, Frequency & Ro	ute Used	3. Therapy D	ates (If	unknown, g	ive duration)
	B. ADVERSE EVENT OR PRODUC	TPROBLE				#1		from/to (or #1	nest es	und()	
		uct Problem (e	e.g., defects/malfu	inctions)				#2			
	 Outcomes Attributed to Adverse Event (Check all that apply) 					#2 4. Diagnosis for Use (Indi	cetion)		Event A	bated Afte	e lleo
	Death:	Disability of	or Permanent Dan	nage			cationy			d or Dose F	
	(mm/dd/yyyy)		Anomaly/Birth D	efect	L	#1		#1	🗌 Ye	es 🗌 No	Doesn't Apply
	L		ious (Important Me		4	#2				[~~]	Doesn't
	Hospitalization - initial or prolonged Required Intervention to Prevent Permai				"	6. Lot#	7. Exp. Date	#2	L Ye	as [] No	Apply
			Report (mm/dd/	·	-	#1	#1			Reappeared	After
	3. Date of Event (mm/dd/yyyy) Un k	4. Date Of This	05/09/2013			#2	#2				Doesn't
	5. Describe Event or Problem				-	9. NDC# or Unique ID					Apply
	Olympus was informed that the							#2	2 🗌 Ye	es 🗌 No	Doesn't Apply
	of their duodenovideoscopes a TJF-Q180V, with the following	-				10. Concomitant Medical	Products and Ther	apy Dates (E	clude fi	reatment of	event)
	2101853, 2101894, and 2000446			1010507		1					
	disinfection and the duodenos			ve for	L						
INK	the following bacteria: Klebs Pseudomonas aeroginosa, and e			or the	L						
	user facility reported that n			er, the							
BLACK	duodenovideoscopes grew all t	chree orga	nisms, but			D. SUSPECT MEDI	CAL DEVICE				
ILA	it was a mix. The user facil one of the 160 duodenovideoso	-	-				IS EVIS EXERA		videc	scope	
SEE	Klebsiella pneumoniae. The us	-		•		2. Common Device Name) Due den erri de				
nS	reported that there were 15 c	cases of p	atient info					oscope			
OR	and they believed that it is	related t	to the			3. Manufacturer Name, C OLYMPUS MEDICAL SY	STEM CORPORATI				
ы	duodenovideoscopes.					2951 Ishikawa-cho,	Hachioji-shi,	Tokyo 192	2-8507	, Japan	
TYPE						4. Model #	Lot#			5. Operato	r of Device
Ξ						TJF-160VF	N/A	n Date (mm/de	dia and	🖌 Healt	h Professional
PLEASE						Catalog # TJF-160VF	Expiration	Unk	<i></i>	🗌 Lay U	Iser/Patient
LE,						Serial #	Other#			Other	:
PJ						2802210	N/A				
						6. If Implanted, Give Date	e (mm/dd/yyyy)	7. If Explan	ted, Giv	re Date (mm	/dd/yyyy)
	6. Relevant Tests/Laboratory Data, Including	Dates				N/A 8. Is this a Single-use De	vice that was Rep	N/A	Reuse	d on a Patie	ant?
						Yes Vo	inter that the test				
						9. If Yes to Item No. 8, Er	nter Name and Add	ress of Repre	ocesso	•	
						N/A					
						10. Device Available for	Evaluation? (Do no	t send to EDA	<u>, </u>		
						Yes No	Returned to M			06/04/:	2013
										(mm/dd/)	
						11. Concomitant Medica	Products and The	rapy Dates (Exclude	treatment o	f event)
	 Other Relevant History, Including Preexist race, pregnancy, smoking and alcohol use, h 	ting Medical C	onditions (e.g., a sfunction, etc.)	llorgies,							
		op 200 0 1 0 1 2 0 0 0 0 0 0 0 0 0 0 0 0 0									
						E. INITIAL REPOR	TER				
						1. Name and Address	Phone	e#			
						Infection Contro	l Nurse				
						NYP Weill Corne:	11 Medical C	enter			
						512 E. 71th Stre					
						New York, NY 100	J & L				
	Submission of a report does not con	stitute an a	dmission that	medical		2. Health Professional?	3. Occupation		4.	Initial Repo	rter Also Sen
	personnel, user facility, importer, dis caused or contributed to the event.	tributor, ma	anufacturer or	r product		🖌 Yes 🔲 No	Administrator/Su	upervisor		Report to F	™DA]No ● Unk.

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							FDA USE ONLY
MEDWATCH	-			-			
FORM FDA 3500	• • •	-		Page			
F. FOR USE BY	USER FACI					ACTURERS ONLY	
1. Check One User Facility	Importe		-/importer R	eport Number	1. Type of Reportable E	/enc	2. If Follow-up, What Type?
3. User Facility or Imp	porter Name/Ad	dress			Serious Injury		Additional Information
					Malfunction		Response to FDA Request
					✓ Other: patien	t infection	Device Evaluation
					3. Device Evaluated by	Aanufacturer?	4. Device Manufacture Date (mm/yyyy)
					Not Returned to		unk
4. Contact Person			5. Phone Nu	Imber		ation Summary Attached	5. Labeled for Single Use?
6. Date User Facility	or 7. '	Type of Report	t	8. Date of This Report	provide code:	<i>to explain why not)</i> or	
Importer Became Aware of Event (mi] Initial	-	(mm/dd/yyyy)			Yes 🗸 No
] Follow-up #			6. Evaluation Codes (Re	fer to coding manual)	
9. Approximate		blem Codes (F		g manual)	Method	10 - 37	38 -
Age of Device	Patient	1705			Booutto	100 -	
	Code	1735 -	' [Results		
	Device Code	1091 -	2303	·	Conclusions	51 -	
11. Report Sent to FD	DA? 1	2. Location W			7. If Remedial Action In	tiated, Check Type	8. Usage of Device
Yes	ld/yyyyy)	Hospita	i	Outpatient Diagnostic Facility		Notification	Initial Use of Device
		Home	Home	Ambulatory Surgical Facility	Repair	Inspection	✓ Reuse
13. Report Sent to Ma	anufacturer?	Outpatie	ent Treatmen		Replace		9. If action reported to FDA under
<u> </u> Yes ∏ No(<i>mm/d</i>	ld/yyyy)	Facility				' Adjustment	21 USC 360I(f), list correction/ removal reporting number:
				(Specify)	Other:		
14. Manufacturer Nar	me/Address					fa stures Nerretive	and / or 11. Corrected Data
					10. 🖌 Additional Manu Evaluation Summ		
G. ALL MANUF	ACTURERS						
1. Contact Office - Na for Devices)	ame/Address <i>(a</i>	nd Manufactu	ring Site	2. Phone Number			
				484-896-5688			
OLYMPUS AMER 2400 Ringwoo	•			3. Report Source (Check all that apply)			
San Jose, CA				Foreign			
OLYMPUS MEDI	CAL SYSTEM	I CORPORAT	ION				
2951 Ishikaw	a-cho, Hac			Literature			
192-8507, Ja	ipan			Health Professional			
4. Date Received by		5.	<u> </u>	User Facility			
Manufacturer (mm	/dd/yyyy)	(A)NDA #		Company Representative			
05/09/2		IND #		Distributor			
6. If IND, Give Protoc	.01#	STN #		Other:			
7. Type of Report		PMA/ 510(k) #					
(Check all that appl		Combination					
5-day 🖌 30-	day rlodic	Product	Yes				
☐ 10-day 🔽 Initi		Pre-1938 OTC Product	Yes				
15-day Fol	llow-up #		Yes				
9. Manufacturer Rep	ort Number	8. Adverse Ev	rent Term(s)				
8010047-2013-	00176						
					」		
minutes per response,	including the tim	e for reviewing	instructions,	en estimated to average 66 searching existing data	Department of Health an Food and Drug Administr	ation	OMB Statement: "An agency may not conduct or sponso and a person is not required to reason
sources, gathering and collection of informatio	d maintaining the	data needed, a ts regarding th	and completing is burden est	ng and reviewing the limate or any other aspect o	Office of Chief Information 1350 Piccard Drive, 420/		"An agency may not conduct or sponso and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control
this collection of inform	nation, including	suggestions for	reducing thi	s purden to:	Rockville, MD 20850	N this form to this addre	number."

Manufacturer Report # 8010047-2013-00176

Section H10.

. 1

The user facility returned one TJF-Q180V with serial number 2101850 along with two TJF-160VFs with serial numbers: 2802210 and 2802201 to Olympus for evaluation. The two TJF-160VFs was received with a torn bending section cover.

All returned duodenovideoscopes were sent to an offsite laboratory for microbiological testing. The TJF-Q180V with serial number 2101850 was tested positive for Klebsiella pneumonia. The two TJF-160VFs did not grow any microorganisms.

Following the microbiological testing the duendovideoscope (subject) was returned to Olympus for physical evaluation. The biopsy port, biopsy channel, suction cylinder and suction channel of the duodenovideoscope were examined with a boroscope and no residue or debris was found. However, a tear in the bending section was noted, which caused the device to fail the leak test. In addition, the subject device had deep scratches on the edge of the distal end cover. The device was recommended for major repair.

As part of our investigation with this report, an Olympus Endoscopy Support Specialist (ESS) visited the user facility to observe the user facility's reprocessing practices and provided reprocessing training per the user facility's request. During the onsite visit the ESS observed that the user facility staff was not pre-cleaning, leak testing, and pressurizing the endoscope before submerging the device in the water. Additionally,the staff was not using the air/water cleaning adapter, nor using the correct suction cleaning adapter.

Please cross reference Mfr. Report# 8010047-2013-00172, 8010047-2013-00173, 8010047-2013-00174, 8010047-2013-00175, and 8010047-2013-00177.



OLYMPUS OLYMPUS ERCP ENDOSCOPE

Back to Search Results

Model Number J180 Event Date 12/20/2012 Event Type Malfunction Event Description

This pt and 15 subsequent pts developed klebsiella pneumoniae infections after having undergone endoscopic retrograde cholangiopancreatogram (ercp) procedures. The problem was thought to be related to difficulty in reliably cleaning and disinfecting the mechanically complex 'elevator' at the distal end of the endoscope. In response, the method of reprocessing was changed from automated high-level disinfection (hld) to gas sterilization. In addition, all staff was re-trained in scope pre-cleaning, cleaning, and high-level disinfection. The re-training and hdl was assessed by obtaining brush specimens of the elevator after hld of 10 ercp scopes that had been used on pts with known infection of the biliary tract. All of these cultures were negative.

Search Alerts/Recalls²³

New Search | Submit an Adverse Event Report²⁴

Brand NameOLYMPUS Type of DeviceERCP ENDOSCOPE Manufacturer (Section D)OLYMPUS Center Valley PA 18034 MDR Report Key3413223 Report NumberMW5032234 **Device Sequence Number**1 Product CodeKOG²⁵ **Report Source**Voluntary **Reporter Occupation**ATTORNEY Type of ReportInitial **Report Date**10/09/2013 2 DeviceS WERE Involved in the Event:12 **0** PatientS WERE Involved in the Event: Date FDA Received 10/10/2013 Is This An Adverse Event Report?No Is This A Product Problem Report? Yes Device OperatorHealth Professional Device MODEL Number J180 Is The Reporter A Health Professional?No Is this a Reprocessed and Reused Single-Use Device?No

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- 1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
- 2. http://www.addthis.com/bookmark.php

MAUDE Adverse Event Report: OLYMPUS OLYMPUS ERCP ENDOSCOPE

- 3. http://www.fda.gov/default.htm
- 4. http://www.fda.gov/MedicalDevices/default.htm
- 5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
- 6. /scripts/cdrh/devicesatfda/index.cfm
- 7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
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- 11. /scripts/cdrh/cfdocs/cfRES/res.cfm
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- 17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
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- 19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
- 20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
- 21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
- 22. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
- 23. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm
- 24. https://www.accessdata.fda.gov/scripts/medwatch/
- 25. ../cfPCD/classification.cfm?start_search=&ProductCode=KOG

Page Last Updated: 09/30/2015

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- 5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
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- 9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
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- 11. /scripts/cdrh/cfdocs/cfRES/res.cfm
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- 20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
- 21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
- 22. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
- 23. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm
- 24. https://www.accessdata.fda.gov/scripts/medwatch/
- 25. ../cfPCD/classification.cfm?start_search=&ProductCode=KOG

Thomas Jefferson University Hospital, Philadelphia, Pennsylvania

U.S. Department of Health and Human Services Food and Drug Administration

MEDWATCH

FDA eSubmitter Generated Form 3500A

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

UF/Importer	Report #:	

Mfr Report #:

Form Code:

A. PATIENT INFORMATION

		4. Weight
B. ADVERSE EVENT OR PRODUCT PROBLEM		
1. [X] Adverse Event and/or [] Product Problem (e.g., defe	cts/malfunctions)	
2. Outcomes Attributed to Adverse Event (Checked all that apply)		· · · · · · · · · · · · · · · · · · ·
 Death Life-threatening Hospitalization - initial or prolonged Required Intervention to Prevent Permanent impairment/D 	[] Disability or Permar [] Congenital Anomaly [] Other Serious (Impo amage (Devices)	/Birth Defect
3. Date of Event (mm/dd/yyyy) 04/18/2013	4. Date of this Report (mm/dd/yyyy) 05/17/2015	
5. Describe Event or Problem		
Olympus was informed that a patient contracted a carba three different ERCP procedures. It was reported that tw perform the patient's procedures on February 28, 2013, procedure on May 21, 2013, the patient began to exper- hospital for observation. The patient was later discharge	vo TJF -Q180V and one TJF-160V Duod April 18, 2013 and May 21, 2013 at diffe ience symptoms of infection with epigast	lenvideoscopes were used to erent user facilities. After, the
On or about May 30, 2013 the patient returned to the us betalactamases (ESBL)-producing Gram-negative bacter patient continues to experience reoccurring pneumonia, have repeated hospital admissions.	eria and was medically treated with antib	iotics. It was reported that the
Olympus followed up with user facility to obtain addition with no results. The exact serial numbers of the duoden	al information regarding the reported ever videoscopes used in the procedure are	ent by telephone and in writing but unknown at this time.
6. Relevant Tests/Laboratory Data, Including Dates		
7. Other Delevent Beter Includier Description Medical Oceanity		
7. Other Relevant History, Including Preexisting Medical Conditions (Pancreatitis	e.g., allergies, race, pregnancy, smoking and alcoh	ol use, hepatic/renal dysfunction, etc.)
C. SUSPECT PRODUCT(S)		
Section C is not applicable to devices.		
D. SUSPECT MEDICAL DEVICE	·	
1. Brand Name	2. Common Device Name	
1. Brand Name EVIS EXERA II Duodenovideoscope	2. Common Device Name Duodenovideoscope, Product C	ode: FDT
EVIS EXERA II Duodenovideoscope		ode: FDT Catalog #
EVIS EXERA II Duodenovideoscope 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEM CORPORATION	Duodenovideoscope, Product C	
EVIS EXERA II Duodenovideoscope 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEM CORPORATION 2951 Ishikawa-cho,	Duodenovideoscope, Product C 4. Model #	Catalog #
EVIS EXERA II Duodenovideoscope 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEM CORPORATION 2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507,	Duodenovideoscope, Product C 4. Model # Unknown	Catalog # Unknown
EVIS EXERA II Duodenovideoscope 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEM CORPORATION 2951 Ishikawa-cho,	Duodenovideoscope, Product C 4. Model # Unknown Serial #	Catalog # Unknown Lot #
EVIS EXERA II Duodenovideoscope 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEM CORPORATION 2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan, JA	Duodenovideoscope, Product C 4. Model # Unknown Serial # Unknown	Catalog # Unknown Lot # N/A
EVIS EXERA II Duodenovideoscope 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEM CORPORATION 2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan, JA 5. Operator of Device Health Professional	Duodenovideoscope, Product C 4. Model # Unknown Serial # Unknown Expiration Date (mm/dd/yyyy) 6. Implanted Date (mm/dd/yyyy)	Catalog # Unknown Lot # N/A Other #
EVIS EXERA II Duodenovideoscope 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEM CORPORATION 2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan, JA 5. Operator of Device Health Professional	Duodenovideoscope, Product C 4. Model # Unknown Serial # Unknown Expiration Date (mm/dd/yyyy) 6. Implanted Date (mm/dd/yyyy)	Catalog # Unknown Lot # N/A Other #
EVIS EXERA II Duodenovideoscope 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEM CORPORATION 2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan, JA 5. Operator of Device Health Professional 8. Is this a Single-Use Device that was reprocessed and Reused on a	Duodenovideoscope, Product C 4. Model # Unknown Serial # Unknown Expiration Date (mm/dd/yyyy) 6. Implanted Date (mm/dd/yyyy)	Catalog # Unknown Lot # N/A Other # 7. Explanted Date (mm/dd/yyyy) ? (Do not send to FDA)
EVIS EXERA II Duodenovideoscope 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEM CORPORATION 2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan, JA 5. Operator of Device Health Professional 8. Is this a Single-Use Device that was reprocessed and Reused on a () Yes (•) No () No Information 9. Reprocessor Name and Address	Duodenovideoscope, Product C 4. Model # Unknown Serial # Unknown Expiration Date (mm/dd/yyyy) 6. Implanted Date (mm/dd/yyyy) Patient? 10. Device Available for Evaluation () Yes () No () No Information [] Returned to Manufacturer 	Catalog # Unknown Lot # N/A Other # 7. Explanted Date (mm/dd/yyyy) ? (Do not send to FDA)
 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEM CORPORATION 2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan, JA 5. Operator of Device Health Professional 8. Is this a Single-Use Device that was reprocessed and Reused on an () Yes (•) No () No Information 	Duodenovideoscope, Product C 4. Model # Unknown Serial # Unknown Expiration Date (mm/dd/yyyy) 6. Implanted Date (mm/dd/yyyy) Patient? 10. Device Available for Evaluation () Yes () No () No Information [] Returned to Manufacturer 	Catalog # Unknown Lot # N/A Other # 7. Explanted Date (mm/dd/yyyy) ? (Do not send to FDA)
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Philadelphia, PA 19109, US	4. Initial Reporter Also	Sent Report to F	DA?	
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F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)				
1. User Facility or Importer	2. User Facility/Importe	er Number		
() User Facility () Importer				
3, 4, and 5. User Facility or Importer Name/Address, Contact Person, and Phone Number	6. Date UF/Importer Be	ecame Aware of E	vent (mm/dd/yyyy)	
	7. Type of Report () Initial () F	ollow-up		
	8. Date of This Report	(mm/dd/yyyy)	9. Approximate Age of Device	
10. Event Problem Codes (<i>Refer to coding manual</i>) Patient Code(s): 1735 - 1994 Device Code(s): 2303	14. Manufacturer Name	e/Address		
11. Report Sent to FDA?	-1			
() Yes () No () No Information				
12. Location Where Event Occurred				
13. Report Sent to Manufacturer?	-			
() Yes () No () No Information				
G. ALL MANUFACTURERS				
G. ALL MANUFACTURERS 1, 2. Contact Office - Name/Address/Phone Number Olympus America 2400 Ringwood Ave San Jose, CA 95131, US	1, 2. (Continued) Manu	facturing Site Ad	dress/Phone for Devices	
1, 2. Contact Office - Name/Address/Phone Number Olympus America 2400 Ringwood Ave San Jose, CA 95131, US 3. Report Source (Check all that apply) []] Foreign []	 1, 2. (Continued) Manu 4. Date Received by Manu 05/17/2015 			
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1, 2. Contact Office - Name/Address/Phone Number Olympus America 2400 Ringwood Ave San Jose, CA 95131, US 3. Report Source (Check all that apply) [] Foreign [] Foreign [] Study [] Study [] Literature [] Company Representative [] Consumer [] Distributor	4. Date Received by Ma 05/17/2015 5. PMA/510(k) K080403	anufacturer (<i>mm/</i>		
1, 2. Contact Office - Name/Address/Phone Number Olympus America 2400 Ringwood Ave San Jose, CA 95131, US 3. Report Source (Check all that apply) [] Foreign [] Foreign [] Study [] Study [] Literature [] Consumer [] Distributor [X] Other: Attorney	4. Date Received by Ma 05/17/2015 5. PMA/510(k) K080403 6. If IND, Give Protocol	anufacturer (<i>mm/</i>	9. Manufacturer Report Number	
1, 2. Contact Office - Name/Address/Phone Number Olympus America 2400 Ringwood Ave San Jose, CA 95131, US 3. Report Source (Check all that apply) [] Foreign [] Foreign [] Foreign [] Study [] Literature [] Consumer [] Consumer [] Johr: Attorney 7. Type of Report [] 5-day [] Type of Report [] Obeth () Death () Death () Malfunction () No Information [] No Information	4. Date Received by Ma 05/17/2015 5. PMA/510(k) K080403 6. If IND, Give Protocol	anufacturer (mm/ I # h(s) / Manufacturer? to Manufacturer	9. Manufacturer Report Number 2951238-2015-00249	
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1, 2. Contact Office - Name/Address/Phone Number Olympus America 2400 Ringwood Ave San Jose, CA 95131, US 3. Report Source (Check all that apply) [] Foreign [] Health Professional [] Study [] User Facility [] Literature [] Company Representative [] Consumer [] Distributor [X] Other: Attorney 7. Type of Report [] 5-day [X] Initial [] Follow-up H. DEVICE MANUFACTURERS ONLY 2. If Follow-up, What Type? () Death [] Correction () Death [] Correction () Malfunction [] Response to FDA Request () No Information [] Device Evaluation [] Device Manufacture Date (mm/dd/yyyy) 5. Labeled for Single Use?	 4. Date Received by Ma 05/17/2015 5. PMA/510(k) K080403 6. If IND, Give Protocol 8. Adverse Event Term 3. Device Evaluated by [] Not Returned 1 () Yes [] Ev (•) No 6. Evaluation Codes (F Method Code(s): Result Code(s): 	anufacturer (mm/ l # n(s) to Manufacturer? to Manufacturer aluation Summa Refer to coding ma	9. Manufacturer Report Number 2951238-2015-00249	
1, 2. Contact Office - Name/Address/Phone Number Olympus America 2400 Ringwood Ave San Jose, CA 95131, US 3. Report Source (Check all that apply) [] Foreign [] Foreign [] Foreign [] Study [] Study [] Literature [] Consumer [] Other: Attorney 7. Type of Report [] 5-day [] 5-day [] 5-day [] 5-day [] 1. Type of Report [] 2. If Follow-up H. DEVICE MANUFACTURERS ONLY 1. Type of Reportable Event [] 0. Correction () Death () Death () Malfunction [] 1 Additional Information [] 2 Device Evaluation [] 3 No Information [] 3 No Information	 4. Date Received by Ma 05/17/2015 5. PMA/510(k) K080403 6. If IND, Give Protocol 8. Adverse Event Term 3. Device Evaluated by [] Not Returned ft () Yes [] Ev (•) No 6. Evaluation Codes (F Method Code(s): 	anufacturer (mm/ l # n(s) to Manufacturer? to Manufacturer aluation Summa Refer to coding ma	9. Manufacturer Report Number 2951238-2015-00249	

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MEDWATCH			UF/Importer Report #:	
FDA eSubmitter Generated Form 3500A	for MANDATOR	CY reporting	Form Code:	
[] Repair [] Inspection [] Replace [] Patient Mon [] Relabeling [] Modification [] Other [] Other	nitoring n/Adjustment	(•) Reuse() Unknown() No Information		
 10. [X] Additional Manufacturer Narrative and/or The device referenced in this report has no coutcome could not be conclusively detern time these reports will be supplemented. As part of our investigation into this report, 29, 2015 to observe their reprocessing pra facility did not have a flushing pump in the The user facility uses a custom Ultrasonic new protocol for the TJF-Q180V. Please see associated medical device reported. 	ot yet been returned to nined at this time. If ad Olympus dispatched a ctices. There was no r reprocessing room. machine to reprocess	Olympus for evaluati ditional and significar an endoscopy suppor eprocessing deviation their endoscopes. Th	nt information t specialist (E ns noted, but e ESS demo	n becomes available at a later ESS) to the user facility on May it was observed that the user
No files attached.				



OLYMPUS MEDICAL SYSTEM CORPORATION DUODENOVIDEOSCOPE Back to Search Results

Lot Number N/A Device Problem No Known Device Problem Event Type Injury Event Description

Olympus received a news article which reported that eight patients tested positive for carbapenemresistant enterobacteriaceae (cre) infections after undergoing a procedure using a duodeno videoscope (model/serial number unspecified) at the user facility. In addition, it was stated the hospital cultured its scopes and found no bacteria matching the strain causing the patient's infections. The exact cause of the patient's outcome cannot be conclusively determined at this time. Originally, (b)(6) 2015 olympus was informed of one patient infection in which the patient was medically treated with antibiotics. Based on the new information received olympus will submit seven mdrs to account for the eight patients. (cross reference: 2951238-2015-00388, 2951238-2015-00389, 2951238-2015-00390, 2951238-2015-00391, 2951238-2015-00392, and 2951238-2015-00393) olympus followed up with the user facility to obtain additional information regarding the reported events by telephone and in writing but with no result.

Manufacturer Narrative

The user facility has not provided the specific model and serial number of the scopes involved into the reported events. Therefore, it is unknown if the user facility has returned the scope to olympus for service or evaluation. As part of our investigation in this report, olympus dispatched an endoscopy support specialist (ess) to the user facility to observe their reprocessing practices. At this time the user facility has not yet scheduled a date for the in-service. If additional and significant information becomes available at a later time these reports will be supplemented please see original associated medical device report: 2951238-2015-00249.

Search Alerts/Recalls²³²³

New Search²⁴ | Submit an Adverse Event Report²⁵²⁴

Brand NameDUODENOVIDEOSCOPE Type of DeviceDUODENOVIDEOSCOPE Manufacturer (Section D)OLYMPUS MEDICAL SYSTEM CORPORATION 2951 Ishikawa-Cho, Hachioji-Shi Tokyo 192-8 507 JAPAN 192-8507 Manufacturer ContactNoemi Schambach 2400 Ringwood Avenue San Jose , CA 95131 (408) 408 -4089 40893550 4089355002 MDR Report Key5030603

Report Number2951238-2015-00387 **Device Sequence Number1** Product CodeFDT²⁶²⁵ Report SourceManufacturer Source TypeLITERATURE, OTHER, USER FACILIT Reporter OccupationOther Type of ReportInitial Report Date08/05/2015 **1** Device Was Involved in the Event **1** Patient Was Involved in the Event Date FDA Received08/25/2015 Is This An Adverse Event Report? Yes Is This A Product Problem Report?No Device Operator Health Professional **Device LOT NumberN/A** Was Device Available For Evaluation?No Is The Reporter A Health Professional? Yes Was the Report Sent to FDA? Event LocationNo Information Date Manufacturer Received08/05/2015 Was Device Evaluated By Manufacturer? Device Not Returned To Manufacturer Is The Device Single Use?No Is this a Reprocessed and Reused Single-Use **Device?** Type of Device UsageReuse

Patient TREATMENT DATA Date Received: 08/25/2015 Patient Sequence Number: 1

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- 4. http://www.fda.gov/MedicalDevices/default.htm
- 5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
- 6. /scripts/cdrh/devicesatfda/index.cfm
- 7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
- 8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
- 9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
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- 12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
- 13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
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- 20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
- 21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
- 22. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
- 23. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm
- 24. https://www.accessdata.fda.gov/scripts/medwatch/
- 25. ../cfPCD/classification.cfm?start_search=&ProductCode=FDT
- 1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
- 2. http://www.addthis.com/bookmark.php
- 3. http://www.fda.gov/default.htm
- 4. http://www.fda.gov/MedicalDevices/default.htm
- 5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
- 6. https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm
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- 9. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
- 10. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
- 11. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm
- 12. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
- 13. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/hde.cfm
- 14. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
- 15. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
- 16. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
- 17. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
- 18. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAssem/assembler.cfm
- 19. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
- 20. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Search.cfm
- 21. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
- 22. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
- 23. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm
- 24. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Search.cfm
- 25. https://www.accessdata.fda.gov/scripts/medwatch/
- 26. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm? start_search=&ProductCode=FDT

Page Last Updated: 09/30/2015

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 Ph. 1-888-INFO-FDA (1-888-463-6332) Contact FDA

TISA.gov 🖂 🚺 🗾 📻 🚥

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C U.S. Department of Health & Human Services

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- 2. http://www.addthis.com/bookmark.php
- 3. http://www.fda.gov/default.htm
- 4. http://www.fda.gov/MedicalDevices/default.htm
- 5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
- 6. /scripts/cdrh/devicesatfda/index.cfm
- 7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
- 8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
- 9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
- 10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
- 11. /scripts/cdrh/cfdocs/cfRES/res.cfm
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- 15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
- 16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
- 17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
- 18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
- 19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
- 20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
- 21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
- 22. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
- 23. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm

- 24. https://www.accessdata.fda.gov/scripts/medwatch/
- 25. ../cfPCD/classification.cfm?start_search=&ProductCode=FDT
- 1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
- 2. http://www.addthis.com/bookmark.php
- 3. http://www.fda.gov/default.htm
- 4. http://www.fda.gov/MedicalDevices/default.htm
- 5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
- 6. https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm
- 7. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
- 8. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm
- 9. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
- 10. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
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- 13. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/hde.cfm
- 14. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
- 15. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
- 16. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
- 17. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
- 18. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAssem/assembler.cfm
- 19. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
- 20. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Search.cfm
- 21. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
- 22. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
- 23. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm
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- 25. https://www.accessdata.fda.gov/scripts/medwatch/
- 26. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm? start_search=&ProductCode=FDT

UCLA Medical Center Los Angeles, California



February 17, 2015

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,



Copies:

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015 See OMB statement on reverse.

U.S. Department of Health and Human Services Food and Drug Administration

MEDWATCH

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

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ane	1	of 2	

Mfr Report # 2951238-2015-00064 UF/importer Report #

EDΔ	lleo	Onl

	FORM FDA 350	0A (2/13)			Page 1	of ²
1	A. PATIENT INF	ORMATION				C. SUSPECT PROD
	1. Patient Identifier	2. Age at Time of Event:		3. Sex	4. Weight Ibs	1. Name (Give labeled stre #1
	In confidence	Date		Male	or kgs	#2
		of Birth:	CT PROBLE	M	rgs	2. Dose, Frequency & Ro
	1. 🗸 Adverse Even	nt and/or 🗌 Pro	duct Problem (e.g., defects/malfi	unctions)	#1
	2. Outcomes Attribu (Check all that app.	ited to Adverse Event				#2
	Death:	01/XX/2015	Disability	or Permanent Da	mage	4. Diagnosis for Use (Indi #1
	Life-threatenin	(<i>mm/dd/yyyy</i>) ng	Congenita	al Anomaly/Birth D	Defect	
	Hospitalization	n - initial or prolonged	Other Ser	ious (Important N	ledical Events)	#2 6. Lot #
		rvention to Prevent Perm	•			#1
	3. Date of Event (mi 10/03/201-	m/dd/yyyy) 4- 01/24/2015	4. Date of This	8 Report (mm/do 01/28/2015		#2
	5. Describe Event or	r Problem	I			9. NDC# or Unique ID
		nformed that a resistant organ	-			
BLACK INK	Endoscopic Re procedure on patient who h doing well. T duodenovideos	etrograde Cholar October 3,2014. Mad the ERCP on The user facilit scopes as a prec	ngiopancrea It was n October 3, cy decommis caution whe	atography (reported th 2014 was sioned all en six othe	ERCP) Mat the not their er	10. Concomitant Medical
g	-	e confirmed to k Lated all their				D. SUSPECT MEDI
3LA	laboratory te investigation	esting, as part	of their i	internal		1. Brand Name EVIS E
USEE	-					2. Common Device Name Doudenovideoscop
Š		later informed t ired. The cause				3. Manufacturer Name, C
OR	-					OLYMPUS MEDICAL SY 2951 Ishikawa-cho,
PLEASE TYPE	facility via	been in ongoing telephone and i	in writing	to obtain	more	4. Model #
ΕH	detailed info	ormation regard	ing the rep	ported ever	nts.	TJF-Q180V Catalog #
EAS						TJF-Q180V
Г						Serial # 2405047
				(Continue o	n nare 31	6. If Implanted, Give Date
	6. Relevant Tests/L	aboratory Data, Includir	ng Dates	(continue o	n page 5)	N/A 8. Is this a Single-use De
						🗌 Yes 📝 No
						9. If Yes to Item No. 8, Er
						10. Device Available for
						11. Concomitant Medica
	7. Other Relevant H race, pregnancy, s	listory, Including Preexi smoking and alcohol use,	sting Medical C hepatic/renal dy	(Continue o conditions (e.g., a sfunction, etc.)		
						E. INITIAL REPOR
						1 Name and Address
						The Regents Univ
						200 UCLA Medical Los Angeles, CA
				(Continue o	n page 3)	Phone #
	Submission of a	report does not co	nstitute an a			2. Health Professional?

personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

2					FDA Use Only
C. SUSPECT PR					
1. Name (Give labeled	strength &	mir/labeler)			
#1					
#2 2. Dose, Frequency &	Route Lie	ed	3. Thera	v Dates (If	unknown, give duration)
				(or best es	
#1					
#2 4. Diagnosis for Use (Indication		#2	5. Event /	Abated After Use
#1	naioaionj			Stoppe	d or Dose Reduced?
#2				#1 [] Ye	es No Apply
6. Lot #	7. E	xp. Date		#2 🗌 Ye	es 🗌 No 🗌 Doesn' Apply
#1	#1				Reappeared After
#2	#2				oduction? es
9. NDC# or Unique ID					Apply
					es No Apply
10. Concomitant Medi	cal Produ	icts and Th	erapy Dates	s (Exclude t	reatment of event)
				(C	ontinue on page 3)
D. SUSPECT ME	DICAL	DEVICE			
1. Brand Name EVIS	S EXER	A II DUC	DENOVID	EOSCOPE	C
2. Common Device N Doudenovideosc				2b. P KOG	rocode
3. Manufacturer Nam	e, City an	d State			
OLYMPUS MEDICAL 2951 Ishikawa-ch				192-850)7, Japan
4. Model #		Lot #			5. Operator of Device
TJF-Q180V		N/A	- Data fr	lddha A	✓ Health Professiona
Catalog # TJF-Q180V		Expiratio	n Date (mm N/A	Lay User/Patient	
Serial #		Unique la	lentifier (UC	DI) #	Other:
2405047 6. If Implanted, Give I	Date (mm	(dhana)	7 If Eve	lanted Gi	ve Date (mm/dd/yyyy)
b. If Implanted, Give I N/A	ale (mm)	Garyyyy)	N/A	ameu, GN	Date (Inniuo/yyyy)
8. Is this a Single-use		hat was Re	processed	and Reuse	d on a Patient?
9. If Yes to Item No. 8		ame and Ar	dress of R	eprocesso	r
	,				-
10. Device Available	for Evalua	tion? (Do r	of send to F		
Yes Valiable	_		Manufactur	-	
					(mm/dd/yyyy)
11. Concomitant Med	ical Prod	ucts and fr	erapy Date	s (Exclude	a batment of eventy
	DTCO			(0	Continue on page 3)
E. INITIAL REPO	SRIER				
The Regents Un 200 UCLA Medie			aliforn	na	
Los Angeles, (
Phone #		Er	nail Address	;	
		¢			
2. Health Profession	al? 3. Oc	cupation		4.	Initial Reporter Also Sen

Nurse

Yes No

4. Initial Reporter Also Sent Report to FDA

Yes No 🖌 Unk.

MEDWATCH

FDA USE ONLY

FORM FDA 3500A (2		Pa	age 2 of ²				
		RTER (Devices Only)	H. DEVICE MANUFAC	CTURERS ONLY			
1. Check One		F/importer Report Number	1. Type of Reportable Event		2. If Follow-up, What Type?		
User Facility [3. User Facility or Importer	Importer		✓ Death Serious Injury Malfunction		Correction Additional Information Response to FDA Request Device Evaluation		
			3. Device Evaluated by Man		4. Device Manufacture Date (mm/yyyy)		
4. Contact Person		5. Phone Number		n Summary Attached	Unk 5. Labeled for Single Use?		
6. Date User Facility or Importer Became Aware of Event (mm/dd/)	7. Type of Repo	rt 8. Date of This Repo (mm/dd/yyyy)	rt No (Attach page to e provide code:		☐ Yes		
	Follow-up #		Patient				
Age of Device Pati Coo	Event Problem Codes (tient	Refer to coding manual) - -	Code Device Code		1802 2303		
Coc	de		Method				
11. Report Sent to FDA? Yes Mo (mm/dd/yyyy) 13. Report Sent to Manufac	/) Hospita	Diagnostic Fac	Conclusions	20 - 92]-[]-[]		
Yes No	Outpat Facility Other:	ient Treatment	Recall 1	ed, Check Type	8. Usage of Device Initial Use of Device Reuse Unknown		
			Other:	Adjustment	and / or 11. Corrected Data		
G. ALL MANUFACT 1. Contact Office (and Mar Name Address OLYMPUS AMERICA II 2400 Ringwood Ave: San Jose, CA 9513 Email Address 4. Date Received by Manufacturer (mm/dd/yy, 01/28/2015 6. If IND, Give Protocol # 7. Type of Report (Check äll that apply) 5-day Ø 30-day 7. Totay Periodic 10-day Ø Initial 15-day Fotlow-up 9. Manufacturer Report Nu 2951238-2015-0006	NC NC NC NC NC ND ND ND ND ND ND ND ND ND ND	3. Report Source (Check all that ap) Foreign Study Literature Ocnsumer Health Professio User Facility Company Representative Distributor Other: 1224033 Yes Yes Yes	(ESS) visited the practices at the u education to the u reprocessing incor The cause of the p If additional info time this report u Cross reference mi 2951238-2015-0006 ,2951238-2015-0007 The filing of this	t been returned ympus Endoscopy site to assess user facility a user facility s nsistencies du patient death i patient death i prmation become will be suppler fr. report num 5,2951238-2015- 68, 2951238-2010 0. s report is not	d to Olympus for y Support Specialist s the reprocessing and provided training and staff. The ESS noted ring the site visit. is unknown at this time. es available at a later mented. Ders: -00066,2951238-2015-00067		
The public reporting burden for minutes per response, includi sources, gathering and mainte	for this collection of inform ling the time for reviewing taining the data needed, a nts regarding this burden	ne Paperwork Reduction Act of 19 nation has been estimated to average instructions, searching existing date and completing and reviewing the co estimate or any other aspect of this ucing this burden to:	e 66 Food and Drug Administration Office of Chief Information Off	n ficer RA) Staff	OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number." RA Staff email address.		

UMass Memorial Medical Center, Worchester, Massachusetts



September 17, 2013

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,

Copies:

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0LYMPUS REGULATORY PAGE 81/83

14083322013 12:41 14083322081

OCA_0001668

Mfr Report # 2951238-2013-00017

UF/Importer Report #

U.S. Department of Health and Human Services Food and Drug Administration

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

MEDWATC	н
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CODM EDA 2500A /1/09)

FORM FDA 350	0A (1/09)			Page	1 of	f 2					FDA Use Only
A. PATIENT INF	FORMATION					C. SUSPECT PRODU	JCT(S)				
1. Patient Identifier			3. Sex	4. Weight	1	1. Name (Give labeled stren	gth & mfr/labeler)				
UNK	of Event: UNK	UNK	Female	UNK Ibs		#1					
	or Date			or		#2					
In confidence	of Birth:	INK	Male	UNK kgs		2. Dose, Frequency & Rou	te Used				ive duration)
B. ADVERSE E	VENT OR PRODUC	T PROBLE	M					1	o (or best es	timate)	
1. 🗸 Adverse Ever	nt and/or Pro	duct Problem (e	e.g., defects/mail	unctions)		#1		#1			
	ited to Adverse Event					#2		#2			
(Check all that app						4. Diagnosis for Use (Indic	ation)			Abated Afte d or Dose F	
Death:	(mm/dd/yyyy)	Disability	or Permanent Da	mage		#1				es 🗌 No	Doesn'
Life-threateni			al Anomaly/Birth I			#2					Doesn'
	on - initial or prolonged		ious (Important N		2	6. Lot #	7. Exp. Date		#2 □ Y	es 🗌 No	Apply
Required Inte	ervention to Prevent Perma	anent Impairmer	nt/Damage (Devic	ces)		#1	#1			Reappeared	After
3. Date of Event (m	m/dd/yyyy)	4. Date of This	s Report (mm/de				#2			es No	Doesn
	Unk		8/28/2013			#2	#2				
5. Describe Event o	r Problem informed that th	ere were t	multinle na	atients		9. NDC# or Unique ID			#2 🗌 Y	es 🗌 No	Doesn Apply
infected with	h an unspecified	bacteria	that was t	raced		10. Concomitant Medical	Products and The	rapy Date	s (Exclude i	reatment of	
back to using	g the duodenovid	eoscope. 2	The			. Conconnant medical	, Jugolo and The				
duodenovideos	scope was reproc endoscope repro	essed usin	ng Cidex OF	PA with							
	endoscope repro ue with reproces	sing of th	here was no	,							
duodenovideos	scope and no rep	orts of ol	ostructions	s or							
difficulty pa	assing the clean scope. Prior to			he		D. SUSPECT MEDIO	CAL DEVICE				
duodenovideo	scope had not be	en used s:	ince Janua	ry 2013.		1. Brand Name	s EVIS EXER		odenovi	deoscor	
1								A 11 D	lodenovi	Lacoscor	
Digmpus conta	acted the user f ormation regardi					2. Common Device Name	Duodenovide	oscope			
	t there were 20					3. Manufacturer Name, Ci OLYMPUS MEDICAL SYS		TON			
5 the unspecif:	ied bacteria. Th	e same ba	cteria was	said to		2951 Ishikawa-cho,			192-8507	7, Japan	
have been is	olated from the			However,		4. Model #	Lot #			5. Operato	or of Device
have been iso there was no	further informa	cion prov.	Idea.			TJF-Q180V	N/A				h Professiona
						Catalog #	Expiratio	on Date (m	m/dd/yyyy)		lser/Patient
PLEASE						TJF-Q180V	Other #			Other	
2						Serial # 2102040	Other #				
						6. If Implanted, Give Date	(mm/dd/yyyy)	7. If Ex	planted, Giv	e Date (mn	n/dd/yyyy)
					4	N/A		N/A			
6. Relevant Tests/L	aboratory Data, Includin	g Dates				8. Is this a Single-use De	vice that was Rep	rocessed	and Reuse	d on a Patie	ent?
						Yes ✓ No 9. If Yes to Item No. 8, En	too blama and Ad	drawn of P		-	
						N/A	ter Name and Ad	aress or R	eprocesso	r	
						10. Device Available for E	Evaluation? (Do n	ot send to	FDA)		
						🖌 Yes 🗌 No	Returned to	Manufactur	er on:	8/28/2 (mm/dd/	
						11. Concomitant Medical	Products and Th	erapy Date	es (Exclude		
7 Other Relevant L	listory, Including Preexi	sting Medical (Conditions (e.a.	allemies	-	Cidex OPA		.,			
race, pregnancy,	smoking and alcohol use,	hepatic/renal dy	sfunction, etc.)			Custom Ultrasonic	Machine				
						E. INITIAL REPOR 1. Name and Address	Phor	e #			
						1. Name and Address	Phon	<i></i>			
							L				
						UMASS Memorial M		er			
						55 Lake Avenue N Worcester, MA 00					
										=	
	report does not co facility, importer, di					2. Health Professional?	L.			Initial Repo Report to F	orter Also Sei DA
caused or contri	ibuted to the event.					Yes 🗌 No	Nurse			Yes	No 🖲 Uni

MEDWATCH

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FDA USE ONLY

FORM FDA 3500	A (1/09) (continued)		Page	2 of	-				
F. FOR USE BY U	USER FAC	CILITY/IMPO	RTER (De	evices Only)	H. DE	EVICE MAN	JFACTURERS ONL	Y		
1. Check One 2. UF/Importer Repo			eport Number	1. Type	e of Reportable	2. If Follow-up, What Type?				
User Facility	Import	ter			Death		Correction			
3. User Facility or Imp	orter Name/A	ddress				Serious Injury		Additional Information		
					J È	Malfunction		Response to FDA Request		
						Other:		Device Evaluation		
					3. Devi	ce Evaluated by	y Manufacturer?	4. Device Manufacture Date		
						Not Returned to	-	(mm/yyyy)		
4. Contact Person			5. Phone Nu	mber		·	luation Summary Attached	XX/2011		
				No (Attach page to explain why not) or		5. Labeled for Single Use?				
6. Date User Facility o	r 7.	Type of Report		8. Date of This Report		provide code:		☐ Yes 🖌 No		
Importer Became Aware of Event (mm	1/dd/yyyy)	Initial	1	(mm/dd/yyyy)				Yes 🖌 No		
-		Follow-up #			6. Eva	uation Codes (Refer to coding manual)			
9. Approximate	· · · · · · · · · · · · · · · · · · ·	oblem Codes (F	Pefer to codin	a manual)		Method	10 - 23	- 37 - 38		
Age of Device						mourou				
	Patient Code	1735 -		-		Results	s 115 -			
	Device	2303 -				Caratust	51			
	Code		L			Conclusions				
11. Report Sent to FDA	4?	12. Location W			7. If Re	medial Action I	nitiated, Check Type	8. Usage of Device		
Yes(mm/dd		Hospital	I	Outpatient Diagnostic Facility		Recall	Notification	Initial Use of Device		
N₀		Home	Home	Ambulatory		Repair		✓ Reuse		
13. Report Sent to Mar	nufacturer?	Nursing	Home ent Treatment	Surgical Facility		Replace	Patient Monitoring	Unknown		
Yes(mm/dd	(Annad)	Facility	and the dutient			Relabeling	Modification/ Adjustment	 If action reported to FDA under 21 USC 360i(f), list correction/ 		
No (minuda	וציציני	Other:		(Specify)		Other:		removal reporting number:		
14. Manufacturer Name	e/Address			(Specity)	-					
					10 17	Additional Ma	nufacturer Narrative	and / or 11. Corrected Data		
								report has been sterilized		
								r evaluation. The		
					inst	rument cha	nnel was examine	d using a borescope and		
								te substances and debris		
G. ALL MANUFA			ing City	2 Phone Munit	was found in the instrument channels, channel mount, and cylinder unit. The distal end plastic cover was cracked					
1. Contact Office - Nan for Devices)	ne/Address (anu manufactur	nig site	2. Phone Number	with nicks and dents. The device failed the leak test,					
OLYMPUS AMERI	CA THC			3. Report Source	4 1			seam of the control body		
2400 Ringwood	•			(Check all that apply)		and at th cracked.	e distal end. T	he bending section glue		
San Jose, CA				Foreign						
	NT 040			Study	As part of our investigation into this report, an					
OLYMPUS MEDIC 2951 Ishikawa				Literature	Olympus Endoscopy Support Specialist has been dispatched to the user facility to reassess the reprocessing					
192-8507, Jap			,		practices.					
				Health Professional				when a wear of the second s		
4. Date Received by Manufacturer (mm/d	(d/www)	5.		User Facility			e of user's repo etermined at thi			
08/28/20		(A)NDA #		Company Representative	insu	fficient r	eprocessing of t	he device could not be		
6. If IND, Give Protoco		IND #		Distributor				ctor to the reported plemented if additional		
		STN#		Other:			comes available			
7		PMA/								
 Type of Report (Check all that apply))	510(k) #								
🗍 5-day 🖌 30-da	ay	Combination Product	Yes							
7-day Perio	dic	Pre-1938	☐ Yes							
🔲 10-day 🗹 Initial		OTC Product	T Yes							
	w-up #									
9. Manufacturer Report	rt Number	8. Adverse Ev	ent Term(s)							
2951238-2013-0	0017									
The public reporting burg	den for this co	llection of inform	ation has bee	en estimated to average 66			nd Human Services	OMB Statement:		
minutes per response, in sources, gathering and n	maintaining the	e data needed, a	nd completin	g and reviewing the	Office of	nd Drug Adminis of Chief Informati		"An agency may not conduct or sponse and a person is not required to respon		
	Send comme	ents regarding this	s burden esti	mate or any other aspect of	1350 P	iccard Drive, 420 le, MD 20850		to, a collection of information unless it displays a currently valid OMB control		
		2488200019 101	. Souchig uns	sarden to.			RN this form to this addre	number."		

OCA_0001670

Universitair Medisch Centrum Utrecht, Netherlands

U.S. Department of Health and Human Services Food and Drug Administration			Mfr Report #: 8010047-2015-00816				
Ū	important distributors		UF/Importer Report #:				
MEDWATCH FDA eSubmitter Generated Form 3500A	for MANDATO		Form Code:				
A. PATIENT INFORMATION							
1. Patient Identifier (In confidence)	2. Age at Time of Event, D	Date of Birth	3. Sex No Informa	4. Weight			
B. ADVERSE EVENT OR PRODUCT PROBLEM							
1. [X] Adverse Event and/or [] Product Pro	blem (e.g., defects/malfur	nctions)					
2. Outcomes Attributed to Adverse Event (Checked a	ll that apply)						
 [] Death [] Life-threatening [] Hospitalization - initial or prolonged [] Required Intervention to Prevent Permaner 	[] Congen [x] Other S						
3. Date of Event (mm/dd/yyyy)		4. Date of this Report (/ 08/19/2015	nm/dd/yyyy)				
5. Describe Event or Problem							
Olympus was informed that eight patients cholangiopancreatography (ERCP) procee The facility is recalling patients. The hospital informed olympus that all TJF No detailed information is available at this	dure using a TJF-Q180 F-Q180V scopes were	V between 1st Jan 2	ter undergoing 015 and 15th /	an endoscopic retrograde Aug 2015.			
6. Relevant Tests/Laboratory Data, Including Dates							
7. Other Relevant History, Including Preexisting Med	ical Conditions (e.g., allergi	es, race, pregnancy, smoki	ng and alcohol use	e, hepatic/renal dysfunction, etc.)			
C. SUSPECT PRODUCT(S)							
Section C is not applicable to devices.							
D. SUSPECT MEDICAL DEVICE							
1. Brand Name		2. Common Device Nan	ne				
1. Brand Name EVIS EXERA II DUODENOVIDEOSCOPE		2. Common Device Nan DUODENOVIDEOS		Code: FDT			
EVIS EXERA II DUODENOVIDEOSCOPE 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEMS CORPORATION	DN			Code: FDT Catalog #			
EVIS EXERA II DUODENOVIDEOSCOPE 3. Manufacturer Name, City and State	DN	DUODENOVIDEOS 4. Model # TJF-Q180V Serial #					
EVIS EXERA II DUODENOVIDEOSCOPE 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEMS CORPORATIO 2951 Ishikawa-cho	DN	DUODENOVIDEOS 4. Model # TJF-Q180V		Catalog #			
EVIS EXERA II DUODENOVIDEOSCOPE 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEMS CORPORATIO 2951 Ishikawa-cho	DN	DUODENOVIDEOS 4. Model # TJF-Q180V Serial #	COPE, Product	Catalog #			
EVIS EXERA II DUODENOVIDEOSCOPE 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEMS CORPORATIO 2951 Ishikawa-cho	DN	DUODENOVIDEOS 4. Model # TJF-Q180V Serial # unk	COPE, Product (Catalog #			
EVIS EXERA II DUODENOVIDEOSCOPE 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEMS CORPORATIO 2951 Ishikawa-cho	DN	DUODENOVIDEOS 4. Model # TJF-Q180V Serial # unk Expiration Date (mm/date)	Vyyyy)	Catalog #			
EVIS EXERA II DUODENOVIDEOSCOPE 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEMS CORPORATIO 2951 Ishikawa-cho Hachiouji-shi, Tokyo 192-8507, JA 5. Operator of Device Health Professional 8. Is this a Single-Use Device that was reprocessed a		DUODENOVIDEOS 4. Model # TJF-Q180V Serial # unk Expiration Date (mm/da Unique Identifier (UDI)	Vyyyy)	Catalog # Lot #			
EVIS EXERA II DUODENOVIDEOSCOPE 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEMS CORPORATIO 2951 Ishikawa-cho Hachiouji-shi, Tokyo 192-8507, JA 5. Operator of Device Health Professional		DUODENOVIDEOS 4. Model # TJF-Q180V Serial # unk Expiration Date (mm/da Unique Identifier (UDI) ; 6. Implanted Date (mm/	COPE, Product (//yyyy) # dd/yyyy)	Catalog # Lot # 7. Explanted Date (mm/dd/yyyy)			
EVIS EXERA II DUODENOVIDEOSCOPE 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEMS CORPORATIO 2951 Ishikawa-cho Hachiouji-shi, Tokyo 192-8507, JA 5. Operator of Device Health Professional 8. Is this a Single-Use Device that was reprocessed a		DUODENOVIDEOS 4. Model # TJF-Q180V Serial # unk Expiration Date (mm/da Unique Identifier (UDI)	COPE, Product (//yyyy) # dd/yyyy)	Catalog # Lot # 7. Explanted Date (mm/dd/yyyy)			
EVIS EXERA II DUODENOVIDEOSCOPE 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEMS CORPORATION 2951 Ishikawa-cho Hachiouji-shi, Tokyo 192-8507, JA 5. Operator of Device Health Professional 8. Is this a Single-Use Device that was reprocessed at () Yes (•) No () No Information	and Reused on a Patient?	DUODENOVIDEOS() 4. Model # TJF-Q180V Serial # unk Expiration Date (mm/doi Unique Identifier (UDI); 6. Implanted Date (mm/doi 10. Device Available for () Yes (•) No () No Information [] Returned to Ma	COPE, Product (//yyyy) # dd/yyyy)	Catalog # Lot # 7. Explanted Date (mm/dd/yyyy)			
EVIS EXERA II DUODENOVIDEOSCOPE 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEMS CORPORATIO 2951 Ishikawa-cho Hachiouji-shi, Tokyo 192-8507, JA 5. Operator of Device Health Professional 8. Is this a Single-Use Device that was reprocessed a () Yes (•) No () No Information 9. Reprocessor Name and Address	and Reused on a Patient?	DUODENOVIDEOS() 4. Model # TJF-Q180V Serial # unk Expiration Date (mm/doi Unique Identifier (UDI); 6. Implanted Date (mm/doi 10. Device Available for () Yes (•) No () No Information [] Returned to Ma	COPE, Product (//yyyy) # dd/yyyy)	Catalog # Lot # 7. Explanted Date (mm/dd/yyyy)			
EVIS EXERA II DUODENOVIDEOSCOPE 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEMS CORPORATIO 2951 Ishikawa-cho Hachiouji-shi, Tokyo 192-8507, JA 5. Operator of Device Health Professional 8. Is this a Single-Use Device that was reprocessed a () Yes (•) No () No Information 9. Reprocessor Name and Address 11. ConComitant Medical Products and Therapy Date	and Reused on a Patient?	DUODENOVIDEOS() 4. Model # TJF-Q180V Serial # unk Expiration Date (mm/doi Unique Identifier (UDI); 6. Implanted Date (mm/doi 10. Device Available for () Yes (•) No () No Information [] Returned to Ma	COPE, Product (//yyyy) # dd/yyyy) r Evaluation? (Do	Catalog # Lot # 7. Explanted Date (mm/dd/yyyy) not send to FDA)			
EVIS EXERA II DUODENOVIDEOSCOPE 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEMS CORPORATIO 2951 Ishikawa-cho Hachiouji-shi, Tokyo 192-8507, JA 5. Operator of Device Health Professional 8. Is this a Single-Use Device that was reprocessed a () Yes (•) No () No Information 9. Reprocessor Name and Address 11. ConComitant Medical Products and Therapy Date E. INITIAL REPORTER 1. Name and Address Universitair Medisch Centrum	and Reused on a Patient?	DUODENOVIDEOS() 4. Model # TJF-Q180V Serial # unk Expiration Date (mm/doing) 0. Implanted Date (mm/doing) 6. Implanted Date (mm/doing) (•) Yes (•) No (•) Yes (•) No (•) Yes (•) No (•) Yes (•) No (•) Yes (•) No (•) Yes (•) No	COPE, Product (//yyyy) # dd/yyyy) r Evaluation? (Do	Catalog # Lot # 7. Explanted Date (mm/dd/yyyy) not send to FDA)			
EVIS EXERA II DUODENOVIDEOSCOPE 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEMS CORPORATIO 2951 Ishikawa-cho Hachiouji-shi, Tokyo 192-8507, JA 5. Operator of Device Health Professional 8. Is this a Single-Use Device that was reprocessed a () Yes (•) No () No Information 9. Reprocessor Name and Address 11. ConComitant Medical Products and Therapy Date E. INITIAL REPORTER 1. Name and Address Universitair Medisch Centrum Heidelberglaan 100	and Reused on a Patient?	DUODENOVIDEOS() 4. Model # TJF-Q180V Serial # unk Expiration Date (mm/da Unique Identifier (UDI); 6. Implanted Date (mm/da 10. Device Available for () Yes (•) No () No Information [] Returned to Ma mt) 2. Health Professional?	COPE, Product (//yyyy) # dd/yyyy) r Evaluation? (Do	Catalog # Lot # 7. Explanted Date (mm/dd/yyyy) not send to FDA)			
EVIS EXERA II DUODENOVIDEOSCOPE 3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEMS CORPORATIO 2951 Ishikawa-cho Hachiouji-shi, Tokyo 192-8507, JA 5. Operator of Device Health Professional 8. Is this a Single-Use Device that was reprocessed a () Yes (•) No () No Information 9. Reprocessor Name and Address 11. ConComitant Medical Products and Therapy Date E. INITIAL REPORTER 1. Name and Address Universitair Medisch Centrum	and Reused on a Patient?	DUODENOVIDEOS(4. Model # TJF-Q180V Serial # unk Expiration Date (mm/da Unique Identifier (UDI); 6. Implanted Date (mm/da 10. Device Available for () Yes (•) No () No Information [] Returned to Ma mt) 2. Health Professional? (•) Yes () No 3. Occupation	COPE, Product (//yyyy) # dd/yyyy) r Evaluation? (Do nnufacturer	Catalog # Lot # 7. Explanted Date (mm/dd/yyyy) not send to FDA) mation			

Food and Drug Administration		For use by user-facilities,		UF/Importer Report #:			
IEDWATCH importers, distributor			Form Code:				
FDA eSubmitter Generated Form 35	00A for MANDAT	OKY reporting					
F. FOR USE BY USER FACILITY/IM	PORTER (Devices Only)						
1. User Facility or Importer		2. User Facility/Importe	r Number				
() User Facility () Importer							
3, 4, and 5. User Facility or Importer Nar Phone Number	me/Address, Contact Person, and	6. Date UF/Importer Bec	came Aware of E	Event (mm/dd/yyyy)			
		7. Type of Report					
		() Initial () Fo	au-wolle				
				0. Annewimete Are of Device			
		8. Date of This Report (ттаа уууу)	9. Approximate Age of Device			
10. Event Problem Codes (Refer to codin	g manual)	14. Manufacturer Name	/Address	•			
Patient Code(s):							
Device Code(s):							
11. Report Sent to FDA?							
() Yes () No () No Infor	mation						
12. Location Where Event Occurred							
13. Report Sent to Manufacturer?		-					
() Yes () No () No Infor	mation						
G. ALL MANUFACTURERS							
1, 2. Contact Office - Name/Address/Pho	one Number	1, 2. (Continued) Manuf	facturing Site Ac	Idress/Phone for Devices			
OLYMPUS MEDICAL SYSTEMS CO	DRP.						
2951 Ishikawa-cho, <u>Hachioji-shi, Tokyo 192-8507, JA</u>							
3. Report Source (Check all that apply)		4. Date Received by Ma	nufacturer (mm/	/dd/yyyy)			
	Health Professional	08/19/2015					
	User Facility	5. PMA/510(k) K080403 6. If IND, Give Protocol #					
	Company Representative Distributor						
[] Other							
7. Type of Report		8. Adverse Event Term	(s)	9. Manufacturer Report Number			
[] 5-day [x] Initial [] Foll	ow-up			8010047-2015-00816			
H. DEVICE MANUFACTURERS ON	Y						
1. Type of Reportable Event	2. If Follow-up, What Type?	3. Device Evaluated by	Manufacturer?				
() Death	[] Correction	[] Not Returned to					
(•) Serious Injury	[] Additional Information	() Yes [] Eva	aluation Summa	ary Attached			
 Malfunction No Information 	[] Response to FDA Request	(•) No		-			
() No Information	 Device Evaluation No Information 						
4 Device Manufacture Data (and data)		A Frank Braklam and F		s (Refer to coding manual)			
4. Device Manufacture Date (mm/dd/yyyy	0	Patient Code(s): 193		s (Reler to cooling manual)			
		Device Code(s): 112					
5. Labeled for Single Use?	motion	Method Code(s): 326					
() Yes (•) No () No Infor	mation	Result Code(s): 3221					
		Conclusion Code(s):					
7. If Remedial Action initiated, Check Ty	/De	8. Usage of Device		9. If action reported to FDA under 21			
	Notification	() Initial Use of De	evice	9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number			
	Inspection	(•) Reuse					
	Patient Monitoring	() Unknown					
[] Relabeling [] [] Other	Modification/Adjustment	() No Information					
L							

Mfr Report #: 8010047-2015-00816

U.S. Department of Health and Human Services Food and Drug Administration	For use by user-facilities,	Mfr Report #:	8010047-2015-00816		
MEDWATCH	importers, distributors and manufacturers	UF/Importer Report #:			
FDA eSubmitter Generated Form 3500A	for MANDATORY reporting	Form Code:			
10. [X] Additional Manufacturer Narrative and/or	r 11. [] Corrected Data				
The exact cause of user's report could not A supplemental report will be submitted if s Please cross-reference the following report	significant and additional information becom	es available later.			
File Attachments					
No files attached.					

University of Pittsburgh Medical Center Presbyterian Hospital Pittsburgh, Pennsylvania

Form Approved: OMB No. 09 10-029 1, Expires 12/31/11 See OMB statement on reverse.

U.S. Department of Health and Human Services Food and Drug Administration		For use by user-facilities, importers, distributors and manufacturers				Mfr Report # 8	Mfr Report # 8010047-2012-00481				
MEDWATCH		for MANDATORY reporting			rting	UF/Importer Report #					
FORM FDA 350				Page 1	of 2					FDA Use Only	
A. PATIENT INF	ORMATION				C. SUS	PECT PRO	DUCT(S)			T DA Dat Only	
1. Patient Identifier 2. Age at Time of Event: or			3. Sex	4. Weight	1. Name (* #1		ength & mfr/labeler)				
In confidence	Date of Birth:		Male	kgs	#2			·			
B. ADVERSE EV	VENT OR PRODUC	CT PROBLE	M		2. Dose, F	requency & Ro	oute Used		y Dates (if u (or best esti	inknown, give duration) mate)	
1. Adverse Even		duct Problem (é		unctions)	#1			#1			
2. Outcomes Attribut (Check all that appl	led to Adverse Event	•		,	#2			#2			
Death:	¥/	Disability o	r Permanent Da	mana	4. Diagnos	sis for Use (Ind	lication)	ľ		oated After Use or Dose Reduced?	
Life-threatenin	(mnVdd/yyyy)		Anomaly/Birth (-	#1					No Doesn't Apply	
	- initial or prolonged		ous (Important M		#2				#2 🗌 Yes	Doesn't	
	vention to Prevent Perma				6. Lot#		7. Exp. Date	L		<u> </u>	
3. Date of Event (mn		4. Date of This			#1		#1		 Event Re Reintrod 	appeared After uction?	
	known		11/19/2012		#2		#2		#1 Yes No Doesn Apply		
5. Describe Event or The user faci	Problem lity reported t	hat 10-13 y	nationts t	hat had	9. NDC# o	r Unique ID			#2 🗌 Yes		
	with the subje		-		10.0	mitant Media-	Products and The			🗠 🗠 Арріу	
	Klebsiella pne rovided regardi				TU. Conco	mitant Medical	Products and the	apy Dates (Cxcabe lie	aument of eventy	
had been prov.	ided to the pat	ients.					CAL DEVICE				
					1. Brand M		CAL DEVICE				
						Olymp	ous EVIS EXER		ODENOVI	DEOSCOPE	
					2. Commo	on Device Name	Duodenoscope	5			
					3. Manufa OLYMPUS	cturer Name, C MEDICAL SY		ON	92-8507,	Japan	
					4. Model #	ŧ	Lot #		5.	Operator of Device	
					TJF-Q18		N/A	B -1- (🖌 Health Professional	
								n Date (mm/ N∕A	'da/yyyy)	Lay User/Patient	
						Serial # Other #		.,		Other:	
					2001160	2001160 N/A					
						nted, Give Date	e (mm/dd/yyyy)	I . '	nted, Give I	Date (mm/dd/yyyy)	
6. Relevant Tests/Lat	boratory Data, Including	g Dates			N/A 8. is this a	Single-use De	vice that was Repr	N/A ocessed an	d Reused o	on a Patient?	
					Yes	<u> </u>					
					9. If Yes to	5 item No. 8, Er	nter Name and Add	ress of Rep	rocessor		
					10. Device	Available for I	Evaluation? (Do not	send to FD.	,		
					🖌 Yes	3 🗌 No	Returned to M	anufacturer	on.	.2/11/2012 (mm/dd/yyyy)	
					11. Conco	mitant Medical	Products and The	rapy Dates	(Exclude tre	eatment of event)	
 Other Relevant His race, pregnancy, sn 	story, Including Preexis noking and alcohol use, h	ting Medical Co nepatic/renal dysf	nditions (e.g., a unction, etc.)	llergies,							
						AL REPOR					
					1. Name a	nd Address	Phone	#			
					200 LOI	resbyteria THROP STRE	ET				
					PILLSD	sburgh, PA 15213					
Submission of a r personnel, user fa caused or contrib	eport does not con icility, importer, dis uted to the event.	stitute an adı stributor, mar	mission that lufacturer or	medical product	2. Health I	_	3. Occupation Other Healthcare	Profession	Re	tial Reporter Also Sent port to FDA Yes No ● Unk.	

PLEASE TYPE OR USE BLACK INK

MEDWATCH FORM FDA 3500A (1/09) (continued) Page 2 of 2 F. FOR USE BY USER FACILITY/IMPORTER (Devices Only) 1. Check One 2. UF/Importer Report Number 3. User Facility or Importer Name/Address 4. Contact Person

7. Type of Report

10. Event Problem Codes (Refer to coding manual)

Hospital

🗌 Home

Other:

Nursing Home

12. Location Where Event Occurred

Outpatient Treatment Facility

Follow-up #

1735

2993

 Date of This Report (mm/dd/yyyy)

Outpatient Diagnostic Facility

Ambulatory Surgical Facility

(Specify)

6. Date User Facility or Importer Became

Approximate Age of Device

11. Report Sent to FDA?

Yes

No No

Yes

No

Aware of Event (mm/dd/yyyy)

Patient

Code Device

Code

(mm/dd/yyyy)

(mm/dd/yyyy)

13. Report Sent to Manufacturer?

14. Manufacturer Name/Address

G. ALL MANUFACTURERS		
 Contact Office - Name/Address (a for Devices) OLYMPUS AMERICA, INC. 2400 Ringwood Avenue San Jose, CA 95131 OLYMPUS MEDICAL SYSTEM 2951 Ishikawa-cho, Had 192-8507, Japan 	nd Manufacturing Site M CORPORATION chioji-shi, Tokyo	2. Phone Number 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional [7] User Facility
4. Date Received by Manufacturer (mn/dd/yyyy) 11/19/2012 6. If IND, Give Protocol #	5. (A)NDA # IND # STN #	Company Representative Distributor Other:
7. Type of Report (Check all that apply) 5-day	PMA/ 510(k) # Product Ves Pre-1938 Yes OTC Product Yes 8. Adverse Event Term(s)	

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

2 c	of 2	
	H. DEVICE MANUFACTURERS ONLY	
	1. Type of Reportable Event	2. If Follow-up, What Type?
	Death	Correction
1	Serious Injury	Additional Information
	Malfunction	Response to FDA Request
		Device Evaluation
	Cther: Klebsiella pneumonia	
	3. Device Evaluated by Manufacturer?	 Device Manufacture Date (mm/yyyy)
	Not Returned to Manufacturer	
1	Yes Evaluation Summary Attached	
	No (Attach page to explain why not) or	5. Labeled for Single Use?
1	provide code:	Yes 🗸 No
	6. Evaluation Codes (Refer to coding manual)	
	Method 10 - 38	
	Results 3233 -	-
	Conclusions 11 -	
1	7. If Remedial Action Initiated, Check Type 8.	Usage of Device
	Recall Notification	Initial Use of Device
		Reuse
	Replace Patient Monitoring	Unknown
	Octobelies Modification/ 9.	If action reported to FDA under
	Adjustment	21 USC 360I(f), list correction/ removal reporting number:
	Other:	
	Other:	
		d / or 11. Corrected Data
	10. 📝 Additional Manufacturer Narrative an	d / or 11. Corrected Data
	10. Additional Manufacturer Narrative an Olympus followed-up with the user	d/or 11. Corrected Data
	10. Additional Manufacturer Narrative an Olympus followed-up with the user additional information regarding facility reported that all potent	d/or 11. Corrected Data facility to obtain this report. The user tially affected patients
	10. Additional Manufacturer Narrative an Olympus followed-up with the user additional information regarding facility reported that all potent had undergone ERCP procedures and	d/or 11. Corrected Data c facility to obtain this report. The user tially affected patients d were transplant
	10. Additional Manufacturer Narrative an Olympus followed-up with the user additional information regarding facility reported that all potent had undergone ERCP procedures and patients. The user facility report	d/or 11. Corrected Data c facility to obtain this report. The user tially affected patients d were transplant cted that 6 ERCP
	10. Additional Manufacturer Narrative an Olympus followed-up with the user additional information regarding facility reported that all potent had undergone ERCP procedures and patients. The user facility repor endoscopes were cultured and 1 of	d/or 11. Corrected Data facility to obtain this report. The user tially affected patients d were transplant ted that 6 ERCP f the endoscopes which
	10. Additional Manufacturer Narrative an Olympus followed-up with the user additional information regarding facility reported that all potent had undergone ERCP procedures and patients. The user facility repor endoscopes were cultured and 1 of is the subject device referenced found to have Klebsiella pneumoni	d/or 11. Corrected Data c facility to obtain this report. The user tially affected patients d were transplant cted that 6 ERCP f the endoscopes which in this report was ta on two separate
	10. Additional Manufacturer Narrative an Olympus followed-up with the user additional information regarding facility reported that all potent had undergone ERCP procedures and patients. The user facility repor endoscopes were cultured and 1 of is the subject device referenced found to have Klebsiella pneumoni occasions after numerous cultures	d/or 11. Corrected Data c facility to obtain this report. The user ially affected patients d were transplant cted that 6 ERCP f the endoscopes which in this report was ia on two separate s. Nevertheless, the
	10. Additional Manufacturer Narrative an Olympus followed-up with the user additional information regarding facility reported that all potent had undergone ERCP procedures and patients. The user facility repor endoscopes were cultured and 1 of is the subject device referenced found to have Klebsiella pneumoni occasions after numerous cultures user facility reported that there	d/or 11. Corrected Data c facility to obtain this report. The user tially affected patients d were transplant cted that 6 ERCP f the endoscopes which in this report was la on two separate s. Nevertheless, the e was no direct evidence
	10. Additional Manufacturer Narrative an Olympus followed-up with the user additional information regarding facility reported that all potent had undergone ERCP procedures and patients. The user facility repor endoscopes were cultured and 1 of is the subject device referenced found to have Klebsiella pneumoni occasions after numerous cultures	d/or 11. Corrected Data c facility to obtain this report. The user tially affected patients d were transplant cted that 6 ERCP f the endoscopes which in this report was la on two separate s. Nevertheless, the e was no direct evidence
	10. Additional Manufacturer Narrative an Olympus followed-up with the user additional information regarding facility reported that all potent had undergone ERCP procedures and patients. The user facility repor endoscopes were cultured and 1 of is the subject device referenced found to have Klebsiella pneumoni occasions after numerous cultures user facility reported that there of the infection being tied to ar As part of our investigation into	d/or 11. Corrected Data e facility to obtain this report. The user tially affected patients i were transplant ted that 6 ERCP f the endoscopes which in this report was is on two separate s. Nevertheless, the e was no direct evidence by particular endoscope.
	10. Additional Manufacturer Narrative an Olympus followed-up with the user additional information regarding facility reported that all potent had undergone ERCP procedures and patients. The user facility repor endoscopes were cultured and 1 of is the subject device referenced found to have Klebsiella pneumoni occasions after numerous cultures user facility reported that there of the infection being tied to ar As part of our investigation into Olympus representatives had been	d/or 11. Corrected Data e facility to obtain this report. The user tially affected patients d were transplant ted that 6 ERCP f the endoscopes which in this report was ta on two separate s. Nevertheless, the e was no direct evidence my particular endoscope. To this report, two dispatched to the user
	10. Additional Manufacturer Narrative an Olympus followed-up with the user additional information regarding facility reported that all potent had undergone ERCP procedures and patients. The user facility repor endoscopes were cultured and 1 of is the subject device referenced found to have Klebsiella pneumoni occasions after numerous cultures user facility reported that there of the infection being tied to ar As part of our investigation into Olympus representatives had been facility to assess the facility's	d/or 11. Corrected Data of facility to obtain this report. The user tially affected patients d were transplant tred that 6 ERCP of the endoscopes which in this report was ta on two separate s. Nevertheless, the was no direct evidence any particular endoscope. This report, two dispatched to the user s reprocessing practices
	10. Additional Manufacturer Narrative an Olympus followed-up with the user additional information regarding facility reported that all potent had undergone ERCP procedures and patients. The user facility repor endoscopes were cultured and 1 of is the subject device referenced found to have Klebsiella pneumoni occasions after numerous cultures user facility reported that there of the infection being tied to ar As part of our investigation into Olympus representatives had been facility to assess the facility's and to perform a device evaluation	d/or 11. Corrected Data c facility to obtain this report. The user tially affected patients d were transplant cted that 6 ERCP f the endoscopes which in this report was ta on two separate s. Nevertheless, the e was no direct evidence by particular endoscope. This report, two dispatched to the user s reprocessing practices on. Additionally, the
	10. Additional Manufacturer Narrative an Olympus followed-up with the user additional information regarding facility reported that all potent had undergone ERCP procedures and patients. The user facility repor endoscopes were cultured and 1 of is the subject device referenced found to have Klebsiella pneumoni occasions after numerous cultures user facility reported that there of the infection being tied to ar As part of our investigation into Olympus representatives had been facility to assess the facility's and to perform a device evaluatic ECRI Institute was also involved	d/or 11. Corrected Data c facility to obtain this report. The user tially affected patients d were transplant cted that 6 ERCP f the endoscopes which in this report was ta on two separate s. Nevertheless, the e was no direct evidence my particular endoscope. This report, two dispatched to the user as reprocessing practices on. Additionally, the in the investigation.
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FDA USE ONLY

This report is being submitted as a Medical Device Report in an abundance of caution.

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, 420A Rockville, MD 20850 Please DO NOT RETURN this form to this address.

CMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."



January 29, 2013

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is a supplemental report for a previously reported 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,

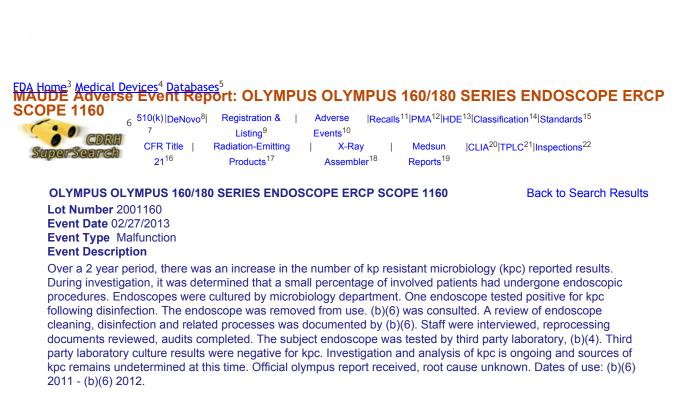


OCA_0001277

			Form	Approved: OMB No	 09 10-029 1, Expires 12/31/11 See OMB statement on reverse.
U.S. Department of Health and Human Services Food and Drug Administration	For use by use	er-facilities,	Mr. Dened #	010047-2012	
MEDWATCH	importers, distributors for MANDATO	and manufacturers RY reporting	UF/Importer Rep	port#	•
FORM FDA 3500A (1/09)	Page 1 c	of 2			EDA Has Only
A. PATIENT INFORMATION		C. SUSPECT PRODU	JCT(S)		FDA Use Only
1. Patient identifier 2. Age at Time	3. Sex 4. Weight	1. Name (Give labeled streng	.,		
of Event:	Female ibs	#1			
Date	□ or	#2			· · · · · · · · · · · · · · · · · · ·
In confidence of Birth: B. ADVERSE EVENT OR PRODUCT PROBLEM	Kga	2. Dose, Frequency & Rout	e Used	3. Therapy Dates from/to (or bes	a (If unknown, give duration) t estimate)
	g., defects/mailunctions)	#1		#1	
2. Outcomes Attributed to Adverse Event	, uneutarinaranteroriaj	#2		#2	
(Check eff that apply)	Democrat Democra	4. Diagnosis for Use (Indica	ition)		nt Abated After Use oped or Dose Reduced?
(mm/dd/yyyy)	Permanent Damage	#1			Yes No Doesn't Apply
	Anomaly/Birth Defect us (Important Medical Evenits)	#2			Yes No Doesn'i
Required Intervention to Prevent Permanent Impairment/			7. Exp. Date		
3. Date of Event (mm/dd/yyyy) 4. Date of This F	Report (mm/dd/yyyy)	#1	#1		nt Reappeared After itroduction?
		#2	#2	#1 [¯_	Yes ☐ No ☐ Doesn't Appiy
5. Describe Event or Problem		9. NDC# or Unique ID		#2	Yes No Doesn't
		1. Brand Name 2. Common Device Name 3. Manufacturer Name, City 4. Model # Catalog #	Lot #	n Date <i>(mm/dd/yyy</i>	6. Operator of Device
					User/Patient
		Serial #	Other#		
		6. If Implanted, Give Date (mm/dd/yyyy)	7. If Explanted,	Give Date (mm/dd/yyyy)
6. Relevant Tests/Laboratory Data, Including Dates		8. Is this a Single-use Devi Yes No 9. If Yes to Item No. 8, Ente			
		10. Device Available for Ev	aluation? (Do not	t send to FDA)	······································
		Yes No [Returned to M	anufacturer on:	(mm/dd/yyyy)
		11. Concomitant Medical P	roducts and The	rapy Dates (Exclu	
 Other Relevant History, Including Preaxisting Medical Cor race, pregnancy, smoking and alcohol use, hepatic/renal dysfe 	nditions (e.g., allergies, Inction, etc.)				
		E. INITIAL REPORT			· •••
		1. Name and Address	Phone	#	
Submission of a report does not constitute an adr personnel, user facility, importer, distributor, man caused or contributed to the event.	nission that medical ufacturer or product	2. Health Professional? 3	. Occupation		 Initial Reporter Also Seni Report to FDA
caused or contributed to the event.		Yes No			Yes No Unk.

MEDWATC	н						FDA USE ONLY
FORM FDA 350	OA (1/09)	(continued)		Page	2 of ²		
F. FOR USE BY			RTER (-	H. DEVICE MANUFA	CTURERS ONLY	· · · · · · · · · · · · · · · · · · ·
1. Check One				Report Number	1. Type of Reportable Even		2. If Follow-up, What Type?
User Facility	Imp			·····	Death		
3. User Facility or im	porter Name	e/Address			Serious Injury		X Additional Information
					Malfunction		Response to FDA Request
							····
					3. Device Evaluated by Man		 Device Manufacture Date (mm/yyyy)
4. Contact Person			5. Phone M	lumber	4 🗵	n Summary Attached	
					No (Attach page to e	•	5. Labeled for Single Use?
6. Date User Facility Importer Became		7. Type of Repo	rt	 Date of This Report (mm/dd/yyyy) 	provide code:		Yes 🚺 No
Aware of Event (m	m/dd/yyyy)	🔲 Inilial			6. Evaluation Codes (Refer I	to coding manual)	
		Follow-up #					
9. Approximate Age of Device	_	Problem Codes (Refer to cod	ing manual)	Meihod		
	Patient Code	I	-		Results		_]+[]+[]
1	Device Code		-	-	Conclusions		
11. Report Sent to FD		12. Location V	/here Event	Occurred	7. If Remedial Action Initiate	ed, Check Type	3. Usage of Device
[_] Yes		- Hospite		Oulpatient Diagnostic Fecility		Notification	Initial Use of Device
	dyyyy)	Home				nspection	Reuse
13. Report Sent to Ma	inufacturer?		; Home ent Trealme	Surgical Facility	Replace F	Patient Monitoring	
Yes	(Anny)	Facilly		in a state of the		Modification/ Adjustment	 If action reported to FDA under 21 USC 360i(f), list correction/
No No	-,,,,,,	Other:		(Specify)	Other:		removal reporting number;
14. Manufacturer Nan	ne/Address	nl/					
G. ALL MANUFA 1. Contact Office - Na for Devices) 4. Date Received by Manufacturer (mm/d 6. If IND, Give Protoco 7. Type of Report (Check all that apply) 5-day 30-d	me/Address dd/yyyyy) ol #		ring Site	2. Phone Number 3. Report Source (Check all that apply) Foreign Study Literature Consumer Health Professional User Facility Company Representative Distributor Other:	the microbiologica the independent la results are pendin	d testing. The boratory shown ng, and this re	he initial results for a initial results from a no growth. The final aport will be is become available.
7-day Perk 10-day Initia 15-day Follo Manufacturer Repo 8010047-2012-0	i w-up # <u>1</u> rt Number	Pre-1938 OTC Product B. Adverse Ev	Yes Yes ent Term(s)				
ninules per response, in ources, gathering and r	ncluding the t mainteining th . Send comm	ime for reviewing he data needed, a lents regarding thi	instructions, ind completing s burden est	mate or any other aspect of	Department of Health and Hun Food and Drug Administration Office of Chisf Information Offi 1350 Piccard Drive, 420A Rockville, MD 20850		OMB Statement: "An agency may not conduct or sponso and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Rockville, MD 20850 Please DO NOT RETURN this form to this address.



Search Alerts/Recalls²³

New Search | Submit an Adverse Event Report²⁴

Brand NameOLYMPUS 160/180 SERIES ENDOSCOPE Type of DeviceERCP SCOPE 1160 Manufacturer (Section D)OLYMPUS 2400 Ringwood Ave. San Jose CA 95131 MDR Report Key2999629 Report NumberMW5029305 Device Sequence Number1 Product CodeFDS²⁵ Report SourceVoluntary Reporter OccupationNurse Type of ReportInitial Report Date03/04/2013 1 Device Was Involved in the Event 1 Patient Was Involved in the Event Date FDA Received03/04/2013 Is This An Adverse Event Report?No Is This A Product Problem Report? Yes Device Operator Health Professional Device LOT Number2001160 OTHER Device ID NumberTJF-Q180V Was Device Available For Evaluation? Device Returned To Manufacturer Date Returned to Manufacturer01/08/2013 Is The Reporter A Health Professional? Yes Is this a Reprocessed and Reused Single-Use Device?No

Patient TREATMENT DATA Date Received: 03/04/2013 Patient Sequence Number: 1

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain

- 2. http://www.addthis.com/bookmark.php
- 3. http://www.fda.gov/default.htm
- 4. http://www.fda.gov/MedicalDevices/default.htm
- 5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
- 6. /scripts/cdrh/devicesatfda/index.cfm
- 7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
- 8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
- 9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
- 10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
- 11. /scripts/cdrh/cfdocs/cfRES/res.cfm
- 12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
- 13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
- 14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
- 15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
- 16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
- 17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
- 18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
- 19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
- 20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
- 21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
- 22. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
- 23. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm
- 24. https://www.accessdata.fda.gov/scripts/medwatch/
- 25. ../cfPCD/classification.cfm?start_search=&ProductCode=FDS

Page Last Updated: 09/30/2015

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💃 U.S. Department of Health & Human Services

Links on this page:

Virginia Mason Hospital and Medical Center Seattle, Washington



August 22, 2014

Food and Drug Administration Center for Devices and Radiological Health Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

Report Type: Manufacturer Report

Dear MDR Coordinator,

Enclosed is an initial 30-day MDR reportable event. Any further correspondence may be directed to my office.

Sincerely,

Copies:

U.S.	Depa	irtmer	t of	Health	and	Human	Services
Food	and	Drug /	\dmi	inistratio	on		

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U.S. Department Food and Drug Ad	of Health and Huma ministration	an Services			r-facilities,	Mfr Rep	port# 295	1238-2014-0	0364	it off feverse
-			importers, distr for MAN	ibutors DATOI	and manufacturers RY reporting	UF/Imp	orter Repor			····-
MedW										
FORM FDA 350			Pa	ige 1 of	f <u></u>				FC	A Use Only
A. PATIENT IN					C. SUSPECT PRO	···· · · · · · · · · · · · · · · · · ·				
1. Patient Identifier	of Event:		3. Sex 4. Weig	int	1. Name (Give labeled sti	rength & mfr/	labeler)			
	or		Female or	lbs	#1					
In confidence	Date of Birth:		Male 0	kgs	#2					
B. ADVERSE E	VENT OR PRODU	CT PROBLE	M		2. Dose, Frequency & R	oute Used	3	Therapy Dates from/to (or best	(lf unknown, giv Stimate)	e duration)
1. 🗸 Adverse Even	t and/or Pro	duct Problem (e.g., defects/malfunctions)		#1			#1		
2. Outcomes Attribu	ted to Adverse Event				#2			#2		
(Check all that app	<i>w</i>		as Domessial Domess		4. Diagnosis for Use (In	dication)	•	5. Even	Abated After led or Dose Re	Use
Death:	(mm/dd/yyyy)	_ []	or Permanent Damage		#1				Yes No	Doesn
Life-threatenin	-		al Anomaly/Birth Defect		#2					Apply
	I - initial or prolonged vention to Prevent Perm		ious (Important Medical E	vents)	6. Lot#	7. Exp. I	Date	#2	Yes 🗌 No	Doesn Apply
3. Date of Event (m		,	s Report (mm/dd/yyyy)		#1	#1		8. Even	Reappeared A	fter
	xx/2013	4. Dute of This	07/25/2014		#2	#2			Yes No	Doesn
5. Describe Event or					9. NDC# or Unique ID					Apply
	nformed of 37 a involving mult		fections at the					#2 🗌	Yes 🗌 No	Doesn' Apply
series/180ser		tible anog	enoscopes (160		10. Concomitant Medic	al Products	and Thera	py Dates (Exclud	treatment of ev	vent)
Four deaths w cause of pati Additionally, infections ba patient's blo Olympus conta writing to ob	ere identified ent deaths is u Olympus was no sed on culture od, bile, uring cted the user i tain more detai	by the use inknown. Diffied of of varian a, or the facility v iled infor	t E.coli from respiratory trac ia telephone and mation regarding	ct.	D. SUSPECT MEE 1. Brand Name Olymmi 2. Common Device Name Duodenovideos co 3. Manufacturer Name, OLYMPUS MEDICAL S 2951 Ishikawa-cho 4. Model #	Dus Duod me ope City and St SYSTEM COL D, Hachio	denovide tate RPORATIO ji-shi, ot#	2b. KC		of Device
the reported provided.	events but no i	further in	formation was		TJF-160VF		/A		Health I	Professiona
provided.					Catalog # TJF-160VF	E	vhiranou n	ate (mm/dd/yyyy)	Lay Us	er/Patient
					Serial #	U	inique Iden	tifler (UDI) #	Other:	
					UNK 6. If Implanted, Give D	ate (mm/dd/)	yyyy)	7. If Explanted,	Give Date (mm/c	id/vvvv)
6 Polevant Testell	boratory Data, Includin	a Datas	(Continue on page	3)						
0. Relevant restart	bolatory Data, includin	ig Dates			8. Is this a Single-use Yes ✓ No	Device that	was Repro	cessed and Reu	sed on a Patien	t?
					9. If Yes to Item No. 8,	Enter Name	e and Addr	ess of Reproces	Sor	
				1	10. Device Available for	or Evaluatio	n? (Do not	send to FDA)		
					Yes 🖌 No	_		anufacturer on:		
					11. Concomitant Medi	cal Product	s and Ther	any Dates (Evel	(mm/dd/yy	
7. Other Relevant H	story, including Press	isting Medical	(Continue on page		TJF-Q180V Seria				of the automotion of the	eveni)
race, pregnancy, s	moking and alcohol use,	hepatic/renal d	Conditions (e.g., allergies ysfunction, etc.)	7					<i>1</i> 0	
					E. INITIAL REPO	BTER			(Continue on	page 3)
1					1. Name and Address					
					Virginia Mason 1100 9th Avenu Seattle, WA 98	ıe	l Cente	r		
							Erre	il Address		
			(Continue on pag	e 3)	Phone #		Ema			
			admission that med	ical	2. Health Professiona	al? 3. Occu	upation		4. Initial Report	er Also Se
caused or contri	facility, importer, d buted to the event.	istributor, m	nanufacturer or proc	uct	🖌 Yes 🗌 No	Physi	cian		Report to FD	

OCA_0001678

MEDW							FDA USE ONLY
FORM FDA 3500				Page 2			
F. FOR USE BY I	USER F		·		H. DEVICE MANUFAC		
1. Check One			F/Importer	Report Number	1. Type of Reportable Event		2. If Follow-up, What Type?
User Facility					Death		
3. User Facility or Imp	orter Nam	e/Address			Serious Injury		Additional Information
					Maifunction		Response to FDA Request
							Device Evaluation
1. S. 1.					3. Device Evaluated by Man	ufacturer?	4. Device Manufacture Date (mm/yyyy)
					Not Returned to Manu	ufacturer	
4. Contact Person			5. Phone	Number	Yes Evaluation	n Summary Attached	UNK
					No (Attach page to exprovide code:	xplain why not) or	5. Labeled for Single Use?
6. Date User Facility o Importer Became	r	7. Type of Repo	rt	 Date of This Report (mm/dd/yyyy) 	provide code.		Yes 🗸 No
Aware of Event (mm	ı/dd/yyyy)	🗌 Initial					-
		Follow-up #			6. Event Problem and Evalu	ation Codes (Refer to	coding manual)
9. Approximate	10. Event	Problem Codes	Refer to co	ding manual)	Patient Code	1735 -	1930 -
Age of Device	Patient [1705			Device	2993 -	
	Code	1735	- 19		Code		
	Device Code	2993	-	-	Method	-	-]-[]
11. Report Sent to FD/		12. Location V	Vhere Ever	t Occurred			
· ·	-	Hospit		Outpatient	Results		
Yes(<i>mm/dd</i>	(yyyy)	Home		Diagnostic Facility	Conclusions	67 -	
13. Report Sent to Mar	nufacturer	2 Nursin	g Home	Ambulatory Surgical Facility	L		3. Usage of Device
· _ `	nunuoturer	Outpat	tient Treatm	• •	7. If Remedial Action Initiat		Initial Use of Device
Yes(mm/dd	Vyyyy)	Facility	, ,			Notification	Reuse
		Other:		(Specify)		Inspection	Unknown
14. Manufacturer Nam	e/Address	and an an an a state of the sta				Patient Monitoring Modification/	9. If action reported to EDA under
						Adjustment	21 USC 360i(f), list correction/ removal reporting number:
					Other:		
					10. 🖌 Additional Manufac	cturer Narrative	and / or 11. Corrected Data
G. ALL MANUFA	CTURE	RS			No devices were r	eturned to Oly	mpus for evaluation.
1. Contact Office (and	Manufact	uring Site for Dev	vices)	2. Phone Number	Olympus offered a	n on-site visi	t to the user facility to
Name							ices, but the user ause of the patient
Address				3. Report Source (Check all that apply)			ly determined. If
OLYMPUS AMERIC	A, INC			Foreign			rmation becomes available
2400 Ringwood				Study	at a later time,	this report wi	ll be supplemented.
San Jose, CA 9	3131				Cross Reference m	fr. Report num	bers:
OLYMPUS MEDICA	L SYSTE	M CORPORAT	ION	Consumer	2951238-2014-0034		
Email Address				Health Professional	2951238-2014-0035 2951238-2014-0035		
4. Date Received by		5.		- 🗸 User Facility	2951238-2014-0035	-	
Manufacturer (mm/d	dd/yyyy)	(A)NDA #		Company	2951238-2014-0035	-	
07/25/2	014	IND #		Representative Distributor	2951238-2014-0035 2951238-2014-0035		
6. If IND, Give Protoco	ol #	BLA#		Other:	2951238-2014-0036		
		-		-	2951238-2014-0036		
7. Type of Report		PMA/ 510(k) # K	024033		2951238-2014-0036		
(Check all that apply 5-day √ 30-d		Combination			2951238-2014-003		
☐ 5-day 🗹 30-d		Product	Ye		2951238-2014-003		
☐ 10-day ✓ initia		Pre-1938	Ye:		2951238-2014-003 2951238-2014-003		
	ow-up #	OTC Produc	t 🗌 Ye	·	2951238-2014-003		
9. Manufacturer Repo	ort Numbe	r 8. Adverse l	Event Term	(s)	2951238-2014-003		
2951238-2014-0	00364				2951238-2014-003	82, and 295123	8-2014-00383
		an and a second se	46 - 2-	and Backwater Are and	Department of Lingth and M	luman Constant	OMP State
				vork Reduction Act of 1995. been estimated to average 66	Department of Health and H Food and Drug Administration	on	OMB Statement: "An agency may not conduct or sponsor, and a person is not
minutes per response, i	including th	e time for reviewin	ng instructio	ns, searching existing data	Office of Chief Information C Paperwork Reduction Act (F		required to respond to, a collection of information unless it displays a currently
of information. Send con	mments re	garding this burde	n estimate	leting and reviewing the collecti or any other aspect of this	PRAStaff@fda.hhs.gov		valid OMB control number."
collection of information	n, including	suggestions for re	ducing this	burden to:	Please DO NOT RETURN	this form to the above	rra Stan email address.

OCA_0001679

For use by user-facilities, .

Mfr Report #: 2951238-2015-00230

UF/Importer Report #:

MEDWATCH	for MANDATO		E		
DA eSubmitter Generated Form 3500A	IOI MANDATO	cr reporting	Form Code:	anna an	
A. PATIENT INFORMATION					
				4. Wei	ight
B. ADVERSE EVENT OR PRODUCT PROBLE	M	11-1-9/0			
1. [X] Adverse Event and/or [] Product Pr		actions)			
2. Outcomes Attributed to Adverse Event (Checked					
 [x] Death: 08/20/2013 (mm/dd/yyyy) [] Life-threatening [] Hospitalization - initial or prolonged [] Required Intervention to Prevent Perman 		[] Congeni [] Other So	y or Permanent ital Anomaly/Birt erious (Importan		
3. Date of Event (mm/dd/yyyy)		4. Date of this Report (n 05/13/2015	nm/dd/yyyy)		
5. Describe Event or Problem					
Olympus received a video clip which rep facility. It was reported that 18 of those p procedures. In addition, it was stated tha pancreatography (ERCP) procedure whi reportedly contracted a drug-resistant sti determined at this time. Originally, Olym Based on the new information received 0 reference 2951238-2015-00230 and 299 Olympus followed up with the user facilit writing but with no result.	atients had expired and t one of the 18 patients ch used an Olympus dur rain of E.coli. The exact pus was informed of 37 Olympus will submit two 51238-2015-00231) y to obtain additional info	seven patients had e who expired, underw odenoscope (model/s cause of the patient's alleged patient infect initial MDRs to accou	expired within 3 ent an endosc serial number u s outcome can tions in which unt for the 39 p	30 days after und copic retrograde unspecified) and not be conclusive 11 patients had e patients. (Please	dergoing their the patient ely expired. cross
6. Relevant Tests/Laboratory Data, Including Dates	H.				
 7. Other Relevant History, Including Preexisting Me Pancreatic cancer and blocked bile duct C. SUSPECT PRODUCT(S) Section C is not applicable to devices. D. SUSPECT MEDICAL DEVICE 		əs, racə, pregnancy, smoki	ng and alcohol use	ə, həpatic/rənal dysfu	nction, etc.)
1. Brand Name Duodenovideoscope		2. Common Device Nan Duodenovideoscope	The second second second	FDT	
3. Manufacturer Name, City and State OLYMPUS MEDICAL SYSTEM CORPORATION	ON	4. Model # Unk		Catalog # Unk	
2951 Ishikawa-cho, Hachioji-shi Tokyo 192-8507, JA		Serial # Unk		Lot # N/A	
		Expiration Date (mm/do	1/уууу)	Other #	
5. Operator of Device		6. Implanted Date (mm/	'dd/yyyy)	7. Explanted Date ((mm/dd/yyyy)
8. Is this a Single-Use Device that was reprocessed () Yes (•) No () No Information	d and Reused on a Patient?	2			
9. Reprocessor Name and Address		10. Device Available fo () Yes (•) No () No Information [] Returned to Ma	L	o not send to FDA)	
11. ConComitant Medical Products and Therapy Da	ates (Excludes treatment of eve	ent)			
E. INITIAL REPORTER					
1. Name and Address Virginia Mason Medical Center		2. Health Professional (•) Yes () No		rmation	
1100 9th Avenue		3. Occupation			

U.S. Department of Health and Human Services		Mfr Report #: 2951238-2015				
Food and Drug Administration	r-facilities, and manufacturers UF/Importer Report #:					
MEDWATCH	for MANDATO					
FDA eSubmitter Generated Form 3500A	an an a color a color a color fa					
Seattle, WA 98101-2756, US Telephone:		Other Health Care	Professional			
Email:		4. Initial Reporter Also	o Sent Report to FD	PA?		
		() Yes () N	o (•) Unknow	n () No Information		
F. FOR USE BY USER FACILITY/IMPORTER	R (Devices Only)					
1. User Facility or Importer () User Facility () Importer		2. User Facility/Impor	ter Number			
3, 4, and 5. User Facility or Importer Name/Addre Phone Number	ss, Contact Person, and	6. Date UF/Importer B	ecame Aware of E	vent (<i>mm/dd/yyyy</i>)		
CA, US		7. Type of Report				
		() Initial ()	Follow-up			
		8. Date of This Report		9. Approximate Age of Device		
		a bate of this tepor		or representation rigo of Dorico		
10. Event Problem Codes (Refer to coding manual	0	14. Manufacturer Nan	ne/Address			
Patient Code(s): 1735 - 1802						
Device Code(s): 2303						
11. Report Sent to FDA?		7				
() Yes () No () No Information						
12. Location Where Event Occurred						
		_				
13. Report Sent to Manufacturer?						
() Yes () No () No Information			in i			
G. ALL MANUFACTURERS 1, 2. Contact Office - Name/Address/Phone Numl		1.2. (Continued) Mar	ufacturing Cite Ad	drass/Phone for Devices		
1, 2. Contact Office - Name/Address/Phone Num	ber	1, 2. (Continued) Man	luracturing Site Ad	dress/Phone for Devices		
OLTIVIEUS AWENICA INC						
2400 Ringwood Avenue						
San Jose, CA 95131, US		1				
3. Report Source (Check all that apply)		4. Date Received by I	Manufacturer (mm/	(dd/yyyy)		
	Professional	05/13/2015				
[] Study [] User Factors [X] Literature [] Compa	acility any Representative	5. PMA/510(k)				
[X] Consumer [] Distribu			and the second second			
[] Other		6. If IND, Give Protoc	ol#			
7. Type of Report		8. Adverse Event Ter	m(s)	9. Manufacturer Report Number		
[] 5-day [X] Initial [] Follow-up			and the second	2951238-2015-00230		
H. DEVICE MANUFACTURERS ONLY						
	low-up, What Type?	3. Device Evaluated				
	Correction Additional Information	[] Not Returned () Yes [] E				
	Response to FDA Request	(•) No	auauon Summa	ary Attached		
	Device Evaluation					
[]	No Information					
4. Device Manufacture Date (mm/dd/yyyy)		6. Evaluation Codes	(Refer to coding ma	anual)		
	Method Code(s): Result Code(s): Conclusion Code(s): 67 - 92					
5. Labeled for Single Use?						
() Yes (•) No () No Information		Conclusion Code(oj. 01 - 92			
7. If Remedial Action initiated, Check Type		8. Usage of Device		9. If action reported to FDA under 21 USC 360i(f), list correction/removal		
[] Recall [] Notifica [] Repair [] Inspec		 () Initial Use of (•) Reuse 	Device	reporting number		
r 1 noben		1-7 110030		and the second sec		

U.S. Department of Health and Human Se Food and Drug Administration	rvices For use by use	-facilities	Mfr Report #:	2951238-2015-00230
MEDWATCH	importers, distributors		UF/Importer Report	t#:
FDA eSubmitter Generated Form 35	for MANDATO	RY reporting	Form Code:	
	Patient Monitoring Modification/Adjustment	() Unknown () No Information	1	
The following five reports will be 2951238-2014-00352, 2951238 2014-00358,2951238-2014-003 2951238-2014-00364, 2951238 2014-00358,2951238-2014-003 2951238-2014-00364, 2951238 2014-00369,2951238-2014-003 2951238-2014-00375, 2951238 2014-00380, 2951238-2014-003	ser facility has returned the scop ympus dispatched an endoscopy vas no reprocessing deviations n isor (AER) and a non-Olympus fin is time, but pre-existing condition and significant information becar e supplemented to change the re -2014-00353, 2951238-2014-00 aining mfr. report numbers: -2014-00348, 2951238-2014-00 59, 2951238-2014-00360, 29512 -2014-00365, 2951238-2014-00 70, 2951238-2014-00371, 29512 -2014-00376, 2951238-2014-00 381, 2951238-2014-00382, 295	v support specialist (E oted, but the user far ushing pump. The ev n of the patients cou omes available at a la port type from seriou 350, 2951238-2014-(238-2014-00361, 295 366, 2951238-2014-(238-2014-00372, 295 377, 2951238-2014-(SS) to the user fa cility was found to act cause of the ruled d not be ruled out ater time these rep s injury to deaths: 20355 and 2951238-2 20351, 2951238-2 20367, 2951238-2 20367, 2951238-2	cility to observe their be using a non-Olympus eported events could not as a contributory factor to borts will be supplemented 38-2014-00357 2014-00356, 2951238- 2, 2951238-2014-00363, 014-00368, 2951238- 2, 2951238-2014-00374
File Attachments	11. 11. 11. 11. 11. 11. 11. 11. 11. 11.			11571 (C.S.
No files attached.				