FDA NEWS RELEASE

FDA warns duodenoscope manufacturers about failure to comply with required postmarket surveillance studies to assess contamination risk

For Immediate Release:

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The U.S. Food and Drug Administration today issued warning letters to all three duodenoscope manufacturers for failing to comply with requirements of federal law under which they were ordered to conduct postmarket surveillance studies to assess the effectiveness of reprocessing the devices.

As part of an ongoing effort to prevent patient infections associated with the transmission of bacteria from contaminated duodenoscopes, the FDA in 2015 ordered (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm) U.S. duodenoscope manufacturers Olympus, Fujifilm and Pentax to conduct a postmarket surveillance study to determine whether healthcare facilities were able to properly clean and disinfect the devices. Specifically, as part of their approved study plans, all three manufacturers are required to conduct a study to sample and culture reprocessed duodenoscopes that are in clinical use to learn more about issues that contribute to contamination, as well as a human factors study to assess how well trained hospital staff are following the reprocessing instructions.

To date, Olympus has failed to commence data collection, and Pentax and Fujifilm have failed to provide sufficient data, as required for their respective studies to sample and culture reprocessed duodenoscopes that are in clinical use. Olympus and Pentax also have not complied with requirements for their respective human factors studies to assess how well hospital staff are following reprocessing instructions; Fujifilm has been meeting its requirements for its human factors study.

“The FDA has taken important steps to improve the reprocessing of duodenoscopes, and we’ve seen a reduction in reports of patient infections, but we need the required postmarket studies to determine whether these measures are being properly implemented in real world clinical settings and whether we need to take additional action to further improve the safety of these devices,” said Jeff Shuren, M.D., director of the FDA’s Center for Devices and Radiological Health. “We expect these device manufacturers to meet their study obligations to ensure patient safety.”

Duodenoscopes are flexible, lighted tubes that are threaded through the mouth, throat and stomach into the top of the small intestine (duodenum) and are used during endoscopic retrograde cholangiopancreatography, a potentially life-saving procedure to diagnose and treat problems in the pancreas and bile ducts. In 2013, the FDA learned about a potential association between multi-drug resistant bacteria and duodenoscopes. Upon further investigation, it became clear that these cases of infection were occurring despite confirmation that device users were following proper manufacturer cleaning and disinfection or sterilization instructions.

Since then, the FDA has worked with all three duodenoscope manufacturers that market duodenoscopes in the U.S. to review validated processing instructions and to take corrective actions to remove and replace models from the market with faulty designs that made them difficult to clean and reprocess. On February 26, 2018, the FDA, Centers for Disease Control and Prevention (CDC), and the American Society for Microbiology (ASM), together with other endoscope culturing experts, released voluntary standardized protocols (/media/111081/download) for duodenoscope surveillance sampling and culturing. For healthcare facilities that choose to implement duodenoscope surveillance sampling and culturing, these protocols can be used to help monitor the quality of a facility's endoscope reprocessing procedures. Adequate monitoring may reduce the risk of infection.

FDA expects that Olympus, Fujifilm and Pentax will submit a plan by March 24, 2018 that outlines how study milestones will be achieved. For the sampling and culturing study, the FDA expects 50 percent of samples collected in the study to be processed by August 31, 2018 and 100 percent by the end of 2018. For Olympus's and Pentax's human factors studies, the agency expects 50 percent of testing to be completed by May 31, 2018 and 100 percent by June 30, 2018. If the companies fail to adequately respond to the warning letter, the FDA may take additional action such as seizure, injunction and civil money penalties.

The FDA continues to work with manufacturers and other stakeholders to improve the safety of duodenoscopes and other reusable medical devices to help protect patients from bacterial infections associated with these medical devices.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information

- Olympus Warning Letter (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ucm600330)
- Pentax Warning Letter (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ucm600342)
- Fuji Warning Letter (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ucm600340)
- Infections Associated with Reprocessed Duodenoscopes (/medical-devices/reprocessing-reusable-medical-devices/infections-associated-reprocessed-duodenoscopes)
- 522 Postmarket Surveillance Studies (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm)

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