Recent Actions by the US Food and Drug Administration

Reducing the Risk of Infection from Reprocessed Duodenoscopes

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KEYWORDS

• FDA • Reprocessing • Duodenoscopes • Infection

KEY POINTS

- US Food and Drug Administration staff outline recent actions undertaken to reduce the risk of infection from reprocessed duodenoscopes.
- Actions such as device design changes and improved reprocessing instructions have improved the safety of these devices, but additional work is needed.
- Looking forward, engagement and collaboration among the wider community of stakeholders will be beneficial toward reducing the risk of infection from reprocessed duodenoscopes. Such a community can address unanswered questions that merit further research and develop tools that can be used by health care facilities to improve the quality of reprocessing at their sites.

INTRODUCTION

The Food and Drug Administration (FDA) is the oldest comprehensive consumer protection agency in the United States. The FDA oversight of food and drugs began in 1906. Since then, Congress has expanded the FDA's role in protecting and promoting the development of human and veterinary drugs, biological products, medical devices and radiation-emitting products, human and animal food, cosmetics, and tobacco. Congress responded to the public's desire for more oversight over medical devices by passing the Medical Device Amendments to the Federal Food, Drug, and Cosmetic

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Act in 1976, and subsequent updates, including the 21st Century Cures Act. The FDA monitors the ongoing safety and effectiveness of regulated marketed medical devices and that includes endoscopes used in gastroenterology procedures.

Endoscopic retrograde cholangiopancreatography (ERCP) procedures combine upper gastrointestinal (GI) endoscopy with fluoroscopic imaging to evaluate—as well as treat—conditions involving the biliary tree and pancreas with a specialized endoscope called a duodenoscope. The unique design of duodenoscopes enables clinicians to perform ERCP procedures. Duodenoscopes have more complex features than other endoscopes, however, which can present significant challenges for reprocessing them in preparation for safe use in subsequent patients. Duodenoscopes contain many small working parts with difficult-to-reach crevices. Therefore, if a duodenoscope is not meticulously cleaned and reprocessed, living microbes harboring in residual tissue or fluid from a prior procedure can be transmitted via the scope to a subsequent patient. In rare cases, this can lead to patient-to-patient transmission of infection.

In the fall of 2013, the Centers for Disease Control and Prevention (CDC) alerted the FDA to a potential association of multidrug-resistant bacteria and duodenoscopes. Since that time, FDA has taken several actions to reduce the risk of infection associated with these life-saving devices. Regulation of these devices, currently available data, and a timeline of FDA's actions are summarized in this article. This article closes by discussing the future of duodenoscope design and use.

PREMARKET EVALUATION OF DUODENOSCOPES

Duodenoscopes are Class II medical devices regulated under 21 Code of Federal Regulations 876.1500, Endoscopes and accessories.[1] Under these regulations, duodenoscope manufacturers must submit 510(k) premarket notifications to the FDA prior to marketing new duodenoscopes in the United States. Duodenoscopes used for ERCP have been in use in the United States prior to the initiation of FDA's regulation of medical devices in 1976. Throughout the ensuing decades, manufacturers have made modifications to duodenoscopes, including but not limited to improved optics, handling, reprocessing methods, material changes, and other design changes. Manufacturers are required to submit to FDA a new 510(k) application for a device modification if the change could affect the safety or effectiveness of the device.

Currently, the FDA's premarket evaluation of duodenoscopes often includes evaluation of the following performance tests or assessments:

- Electrical safety
- Thermal safety
- Electromagnetic compatibility
- Optical performance tests
- Functionality tests
- Mechanical tests
- Biocompatibility
- Reprocessing validation
- Human factors
- Postmarket adverse event and recall reporting information

Prior to 2015, in accordance with the then-current FDA guidance document, "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance," dated April 1996, 510(k) premarket submissions included statements attesting to FDA that the device manufacturer had or would complete

reprocessing validation to support their reprocessing instructions for use. Section 3059 of the 21st Century Cures Act of 2016 (Public Law 114–255) required the FDA to publish a list of reusable medical devices for which validated reprocessing instructions and the validation data for reprocessing of the reusable device must be included in a 510(k) submission. This section of the Act also gives FDA the authority to render a 510(k) decision that these reusable devices are not substantially equivalent to a predicate device, if the validated instructions for use and reprocessing validation data submitted as part of the 510(k) are inadequate. Duodenoscopes were included in the list of reusable medical devices published in the *Federal Register* on June 9, 2017 (82 FR 26807).[2]

Duodenoscope manufacturers typically include in 510(k) submissions durability testing to assess the impact of multiple simulated clinical and reprocessing uses on the functionality of the device; however, the test methodology varies among different duodenoscope manufacturers.

DUODENOSCOPE DESIGN

Most duodenoscope models marketed in the United States are reusable medical devices and require the user to process (ie, clean and high-level disinfect [HLD] or sterilize) the device for initial use as well as reprocess the device after each use.

The availability of different duodenoscope models and designs in the United States is changing. In the past few years, some duodenoscope models were withdrawn from the market, while at the same time new duodenoscope models have gained marketing clearance.

Design Aspects of Duodenoscopes Marketed in the United States

The duodenoscope has a complex device design, which presents a particular challenge to cleaning, HLD, and sterilization. Duodenoscopes are more complex than most other endoscopes, such as gastroscopes or colonoscopes, in that the device contains a working channel that comes off the side of the scope to allow cannulation of the bile duct under direct visualization. Unlike most other endoscopes, duodenoscopes have a movable elevator mechanism at the tip. Raising the elevator mechanism changes the angle of the accessory instrument exiting the instrument channel, allowing the instrument to access and treat problems with fluid drainage from the bile ducts or pancreas. The FDA's engineering assessment and literature review, however, have identified the elevator mechanism as a feature that makes reprocessing of duodenoscopes challenging.[3] For example, 1 step of the manual cleaning instructions in the device's labeling is to brush the elevator area. The moving parts of the elevator mechanism introduce microscopic crevices that may not be reached with a brush. Failure to remove all body fluids and organic debris may result in persistent microbial contamination of the device. Microbes may survive in residual body fluids and organic debris despite immersion of the duodenoscope in HLD solution, potentially exposing subsequent patients to infectious organisms.

Elevator Wire Channel

Duodenoscopes have a long thin wire that connects the elevator control mechanism (on the control handle) to the elevator at the distal tip of the endoscope (the end inserted into the patient). That wire is housed in a narrow channel called the elevator wire channel, which spans from the distal tip to the control handle. Manipulating the elevator control on the control handle moves the elevator wire and subsequently

moves the elevator mechanism at the distal end of the scope. In some models of duodenoscopes, the elevator wire channel is open or unsealed allowing patient body fluids or organic debris to enter the elevator wire channel. That open elevator wire channel requires reprocessing by flushing detergent into the channel for cleaning, followed by the flushing of HLD into the channel for HLD. Newer designs with closed or sealed elevator wire channels eliminate the requirement to reprocess the elevator wire channel.

Currently, only the Olympus TJF-160VF/F, the Olympus JF-140F, and the Olympus PJF-160 have open elevator wire channels. As discussed later, the remaining reusable duodenoscope models have a closed or sealed-off elevator wire channel, which is intended to prevent soil from entering this channel.

The FDA worked closely with all 3 manufacturers of reusable duodenoscopes in the United States (Fujifilm, Olympus, and Pentax) as they evaluated the sealing mechanisms for the elevator wire channels in their duodenoscopes. All 3 manufacturers made design changes to provide an additional margin of safety in an effort to reduce the risk of fluid ingress and cross-contamination. After FDA clearance of these devices with the design changes, these companies conducted recalls to bring the duodenoscopes up to the new specifications: Olympus TJF-Q180V (K143153, cleared in January 2016), Fujifilm ED-530XT (K152257, cleared in July 2017), and Pentax ED-3490TK (K161222 cleared in February 2018; previously cleared in K092710).

All new reusable duodenoscope models with sealed elevator wire channels are expected to undergo robust performance testing to demonstrate adequate sealing, which is important to ensure that the design requirement is met (21 Code of Federal Regulations 820.30).

Accessibility to Crevices at the Distal End

As discussed at the May 2015 panel meeting, the FDA engineering assessment revealed similarities among the 3 reusable duodenoscopes manufacturers' designs for sealing off the elevator wire channel. Very small crevices in the elevator recess and features, such as the O-ring, were exposed to patient soil. It is important to thoroughly clean these areas of the device to remove soil prior to subsequent processing of the device. A recent design change was implemented to improve accessibility to these crevices.

In addition, duodenoscopes are available with either fixed or removable distal caps. Distal caps are made of plastic, rubber, silicone, or other soft materials to cover the metal edges on duodenoscope distal ends to prevent tissue injury from the metal edges. Fixed endcap duodenoscopes have the cap permanently glued to the metal edges around the distal end, whereas removable distal caps remain on the duodenoscope by tension/friction.

During reprocessing, removable distal caps allow greater access to the elevator, including the underside of the elevator. This removable distal cap design is expected to improve the ability to clean the elevator recess and thus improve the safety of these devices.

Duodenoscopes with removable caps also eliminate the need for adhesive under the cap. As noted in FDA January 2017 Safety Communication,[4] cracks and gaps in the adhesive that seals the fixed distal caps can occur over time with repeat use. These cracks or gaps can lead to microbial and fluid ingress. These areas can be challenging to clean and HLD and may increase the risk of infection transmission among patients.

FOOD AND DRUG ADMINISTRATION TIMELINE OF INVESTIGATIONS INTO OUTBREAKS AND ACTIONS

Some of the activities in the FDA's investigation of duodenoscope-associated infections are summarized. This is not intended to be a comprehensive list of FDA activities or actions, but rather a general overview.

Fall 2013–Winter 2014

The CDC alerted the FDA to a potential association between patients experiencing multidrug-resistant bacteria infections after ERCP procedures with duodenoscopes. Upon further investigation, the FDA learned that these new cases of infection were occurring despite confirmation that the users were following proper manufacturer cleaning and disinfection or sterilization instructions. The FDA communicated with federal partners, manufacturers, and other stakeholders to better understand the critical factors contributing to these infections and how to best mitigate them.

The FDA began reviewing the 510(k) history of all duodenoscope manufacturers and completed an analysis of the adverse events submitted to FDA to identify trends associated with the duodenoscopes identified. An effort also was conducted to identify all HLD manufacturers and review the data to ensure that biofilm formation was not an issue. The FDA began working with the CDC and US Environmental Protection Agency (EPA) to develop testing methods and a protocol to analyze different HLDs; this project concluded in 2014.

Spring–Fall 2014

Requests for information (RFIs) were distributed to the duodenoscope manufacturers and responses were received and reviewed. The FDA worked interactively with duodenoscope manufacturers, reviewing their validation study protocols and analyzing data from their cleaning HLD studies and recommending more rigorous testing with more robust cleaning and HLD protocols to enhance the safety margin associated with duodenoscopes use. The FDA repeatedly interacted with manufacturers to identify design features that may have contributed to the transmission of infection. The FDA also conducted a survey of a collaborative network of clinical sites to assess duodenoscope use and gathered information from hospitals regarding the use of HLDs used for reprocessing compared with sterilization capabilities with ethylene oxide. Duodenoscope surveillance culturing was discussed at the CDC Healthcare Infection Control Practices Advisory Committee public meeting. Collaborative evaluation with the EPA to assess effectiveness of HLDs was conducted.

Winter–Spring 2015

The FDA conducted an evaluation of automated endoscope reprocessors (AERs), including interactive review of manufacturer validation study protocols, analysis of data from cleaning and HLD or liquid chemical sterilization studies, and recommendation for additional, more rigorous testing with more robust reprocessing protocols to enhance the safety margin associated with duodenoscopes. Additional Medical Product Safety Network interviews with hospital facilities that experienced clusters or outbreaks of antibiotic-resistant bacterial infections related to ERCP procedures were performed.

May 2015 and Subsequent Actions

In May 2015, the Gastroenterology and Urology Devices Panel met to discuss the reported outbreaks of infections associated with the use of duodenoscopes during

ERCP procedures.[5] A summary of panel recommendations and FDA's subsequent activities is provided.

- The panel unanimously agreed that ERCP is an important procedure, and the benefits of ERCP outweigh the risk associated with the use of duodenoscopes in appropriately selected patients; however, the panel found that duodenoscopes and AERs did not provide an acceptable level of effectiveness and safety. During the panel meeting, there was a proposal to move toward sterilization rather than HLD of duodenoscopes, but sterilization was not unanimously recommended.
  - FDA action
    To address questions regarding the safety and effectiveness of current duodenoscope reprocessing practices, in October 2015, the FDA ordered the 3 duodenoscope manufacturers to conduct 2 postmarket surveillance studies: a human factors validation study for the reprocessing instructions and a microbiological sampling and culturing study. The FDA tracked progress and results from those studies and in March of 2018, the FDA issued warning letters to the duodenoscope manufacturers for failing to comply with the postmarket surveillance study.
- The panel agreed that manual cleaning, in particular the brushing of channels and elevators, is a critical step in reprocessing duodenoscopes to ensure the removal of debris and subsequent proper disinfection or sterilization. Furthermore, to ensure manual cleaning is conducted properly and that users can follow the numerous complex steps, the panel recommended additional training for reprocessing personnel at health care facilities and the incorporation of human factors testing to evaluate reprocessing instructions.
  - FDA action
    In accordance with panel recommendations, the FDA requested that the manufacturers provide updated and newly validated duodenoscope reprocessing instructions that included an emphasis on effective cleaning of the elevator recess and additional brushing and flushing steps.
- The panel agreed that human factors testing for reprocessing instructions was important to ensure reprocessing personnel will comprehend and correctly follow reprocessing instructions in the labeling.
  - FDA action
    As recommended by the panel, all reusable duodenoscopes that have subsequently been cleared by FDA have included human factors validation testing of duodenoscope reprocessing instructions in the premarket submission, or human factors testing was ordered in postmarket studies.
- The panel discussed the CDC 2015 interim guidelines on surveillance for contamination of duodenoscopes after reprocessing. The panel concluded that more data and validation testing was needed before a surveillance program should be implemented by health care facilities.
  - FDA action
    To address concerns about the lack of validation for sampling and culturing methods, the FDA worked with the CDC, the American Society for Microbiology, and other experts to develop a protocol for surveillance sampling and culturing of duodenoscopes. This protocol, which was used by duodenoscope manufacturers as part of their postmarket surveillance studies, was released publicly in February 2018 (https://www.fda.gov/media/111081/download).

- The panel identified the need for development and validation of cleaning verification assays.
  - FDA action
    To address the lack of validation and FDA clearance for cleaning verification assays, the FDA contacted manufacturers of adenosine triphosphate test systems advising them of the importance for manufacturing, testing, and labeling for medical devices promoted for assessing duodenoscope cleaning.
- The panel discussed informed consent and patient selection and recommended disclosure of the risks and alternatives to ERCP.
  - FDA action
    In line with the panel's recommendations for transparency on the risks of ERCP, the FDA requested that duodenoscope manufacturers include in the revised device labeling the observed contamination rates from the postmarket studies.
- The panel recommended that manufacturers should be encouraged to redesign duodenoscopes to allow for thorough cleaning, disinfection, and sterilization.
  - FDA action
    In line with the panel's recommendation for duodenoscope designs that allow for thorough reprocessing, the FDA requested changes to duodenoscope design to reduce the risk of ingress of fluids in sealed-off areas of the device. The FDA also requested that duodenoscope labeling be revised and include recommendations for annual inspection to identify and replace worn and damaged parts. The FDA subsequently has cleared duodenoscopes with disposable endcaps, which allow greater access for cleaning the elevator as well as a fully disposable duodenoscope, both of which are expected to have improved safety profiles relative to fixed endcap duodenoscopes.
- The panel urged the FDA to provide early communication of the facts to the public in situations when the FDA has a medical device concern but not enough information to determine the most appropriate action toward a resolution.
  - FDA action
    As recommended by the panel, the FDA issued multiple public communications to disclose currently available data. For example, following the panel meeting, the FDA issued an August 2015 communication of supplemental measures to enhance duodenoscope reprocessing that emerged from the May 2015 panel meeting. These optional supplemental measures that may be implemented by health care facilities include double HLD, sampling and culturing of duodenoscopes, ethylene oxide sterilization, and liquid chemical sterilization. The FDA also publicly communicated on the interim postmarket surveillance study data, which are discussed in more detail later.

In addition to the activities recommended by the panel, the FDA has continued regulatory oversight. The FDA has conducted directed inspections of the 3 US duodenoscope manufacturers, and, after the inspections, the FDA has issued warning letters for regulatory violations, when appropriate.

NOVEMBER 2019 PANEL MEETING

In November 2019, the General Hospital and Personal Use Devices Panel met to discuss the current infection, contamination, and postmarket duodenoscope data

as well as current technological design advancements that potentially could enhance the safety of these devices.[6] The FDA relayed concerns that current practices for reprocessing duodenoscopes are not sufficient to avoid infections associated with ERCP. The following information was presented:

- Adverse event reports that were submitted to FDA indicate a decrease in the number of reported infections, with a concurrent increase in reports of contaminated duodenoscopes. The decrease in infections suggests that efforts to reduce the risk of infection from duodenoscopes have yielded improvements; however, additional improvements will be important to decrease the risk of infection further. Sampling and culturing of duodenoscopes after reprocessing were identified as supplemental measures to enhance duodenoscope reprocessing at the 2015 FDA panel meeting; the marked increase in reports of contamination may be due to the increasing number of facilities conducting duodenoscope sampling and culturing since 2015.
- Results from the FDA-mandated postmarket surveillance studies conducted by duodenoscope manufacturers showed that up to 6% of reprocessed duodenoscopes were contaminated with high-concern organisms (organisms that are associated more often with infections). The percent of contaminated samples shows that improvements are necessary to better assure patient safety. Initial root cause analyses suggest that some factors that may contribute to device contamination after reprocessing include device damage and errors in reprocessing; however, additional data are needed.
- Results of human factors validation testing of the reprocessing instructions indicated that current reprocessing user materials are difficult for reprocessing staff to read, understand, and follow. Study participants experienced difficulties and multiple failures in achieving adequate reprocessing tasks. Therefore, current reprocessing user materials do not adequately support user understanding and adherence to reprocessing instructions.

The panel was asked to comment on FDA's previous actions and whether the trajectory that FDA had taken to reduce the risk of infections continued to be appropriate. The consensus of the panel was that training of reprocessing personnel was of utmost importance. The panel recognized that such training falls outside of FDA's purview; nonetheless, FDA was encouraged to collaborate with manufacturers, accrediting organizations, and other stakeholders to ensure correct reprocessing of duodenoscopes in health care settings. Some panel members commented that the magnitude of the problem did not raise concerns and that FDA mandates on strategies to reduce the risk of infection for duodenoscopes would not be helpful. The panel recommended that the FDA carefully consider next steps and make deliberate decisions.

The FDA discussed standardizing duodenoscope durability testing that is conducted by the manufacturer. The panel's consensus was that standardized durability testing was appropriate, because damage to the duodenoscopes often was not recognized by health care personnel. The panel noted that the details of the durability testing should be further discussed and refined with industry.

The panel discussed the potential of new designs to reduce duodenoscope contamination rates and the urgency with which the transition should be made. The panel's consensus was that although new device designs have the potential to reduce contamination, at that time there were insufficient data to demonstrate that reduction. The panel commented that additional modifications to the device design and reprocessing instructions, education, and practices could be made.

The panel was asked to comment on the appropriate balance between obtaining data premarket versus postmarket for assessing devices that are intended to reduce the risk of infection from duodenoscopes. The panel noted that new device designs need to demonstrate effectiveness in reducing the risk of contamination prior to being available for use; however, the panel recognized the challenges associated with generating such data prior to marketing.

The panel discussed the adequacy/margin of safety for HLD as well as the challenges and benefits of sterilization for routine duodenoscope reprocessing. The panel's consensus was that cleaning is the most important step in duodenoscope reprocessing. The panel noted that in properly cleaned duodenoscopes, HLD is appropriate; however, panel members acknowledged that reports indicate that duodenoscopes are not cleaned properly. The panel also discussed the challenges of implementing sterilization of duodenoscopes, such as potential decreased patient access to ERCPs and increased costs.

FUTURE DIRECTIONS

Duodenoscopes serve a critical, and sometimes life-saving, function in evaluation and treatment of patients with biliary and certain pancreatic diseases. The FDA believes the benefits of the availability of duodenoscopes to perform the ERCP procedure outweigh the risks in appropriately selected patients. The decreased number of reported infections since 2015 is encouraging and indicates that the efforts to reduce the risks of infections have had success; however, the FDA continues to receive reports of infections, which means there is a continued need to improve the safety of reprocessed duodenoscopes. The FDA seeks to further improve the safety of ERCP by addressing the challenges associated with duodenoscope reprocessing due to its complex design and reprocessing challenges.

Several strategies have already been implemented to reduce the risk of duodenoscope contamination, including

- Validated revisions to reprocessing instructions to include rigorous cleaning of the elevator recess
- Design changes to reduce the risk of inadvertent fluid ingress into the duodenoscope and clearance of duodenoscopes with disposable components
- Collection of postmarket surveillance data to assess the effectiveness of current reprocessing practices on devices in use and new device designs
- Human factors evaluation of reprocessing instructions
- Development of a validated protocol for duodenoscope sampling and culturing
- Public communications to disclose currently available data
- Compliance activities, such as inspections and warning letters, to ensure duodenoscope design and manufacturing are in accordance with US quality systems requirements

Some activities are ongoing:

- Ensuring that cleaning verification assays have been appropriately validated
- Requesting transparency in labeling by including the observed contamination rate
- Publicly communicating on the need to transition to newer models of duodenoscopes that simplify or eliminate cleaning

The FDA believes the best solution to reducing the risk of disease transmission by duodenoscopes is through innovative device designs that make reprocessing easier,

more effective, or unnecessary. As stated in the August 2019 Safety Communication,[7] the FDA now is recommending that hospitals and endoscopy facilities transition away from fixed endcap duodenoscopes to those with newer design features that facilitate or eliminate the need for reprocessing. The FDA recommends health care facilities consider making the transition to those devices when they become available. To verify that the new designs reduce the contamination rate, the FDA also has ordered the manufacturers of reusable duodenoscopes with disposable endcaps to conduct new postmarket surveillance studies. Upon completion of these postmarket surveillance studies, the FDA expects the labeling to be updated with contamination rate data.

The FDA recognizes that a transition away from conventional duodenoscopes to the newer, innovative models will take time due to cost and market availability. Health care facilities looking to make a transition to newer designs of devices may have questions about demonstrated benefits to those newer devices. The FDA encourages health care facilities purchasing new duodenoscopes to begin developing a transition plan and work to replace their conventional duodenoscopes with newer models.

In addition to technological advancements, engagement and collaboration among the wider community of stakeholders also will be beneficial toward reducing the risk of infection from reprocessed duodenoscopes. Such a community can raise awareness of the importance of duodenoscope cleaning, work to improve reprocessing training, identify the most pressing unanswered questions that merit further research, and also develop tools that can be used by health care facilities to improve the quality of reprocessing at their sites. The FDA looks forward to working with the community to further reduce the risk of infections from reprocessed duodenoscopes.

REFERENCES

1. U.S. Code of Federal Regulations Title 21, 876.1500 Endoscopes and accessories. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=876.1500. Accessed May 8, 2020.
2. U.S. Federal Register Notice, Volume 82, No. 110. Available at: https://www.govinfo.gov/content/pkg/FR-2017-06-09/pdf/2017-12007.pdf. Accessed May 8, 2020.
3. U.S. Food and Drug Administration. FDA Executive Summary Prepared for the May 14-15, 2015 meeting of the Gastroenterology-Urology Devices Panel of the Medical Devices Advisory Committee. Available at: https://wayback.archive-it.org/7993/20170113091323/http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/UCM445592.pdf. Accessed May 8, 2020.
4. U.S. FDA Safety Communication. Available at: https://www.fda.gov/medical-devices/safety-communications/update-importance-following-validated-reprocessing-instructions-pentax-ed-3490tk-video-duodenoscopes. Accessed May 8, 2020.
5. U.S. Food and Drug Administration. 2015 Materials of the Gastroenterology-Urology Devices Panel. Available at: https://wayback.archive-it.org/7993/20170112002249/http:/www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/ucm445590.htm. Accessed May 8, 2020.
6. U.S. Food and Drug Administration. November 6-7, 2019: General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee Meeting Announcement. Available at: https://www.fda.gov/advisory-committees/advisory-committee-calendar/november-6-7-2019-general-hospital-

and-personal-use-devices-panel-medical-devices-advisory-committee#event-materials. Accessed May 8, 2020.
7. U.S. Food and Drug Administration. The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication. Available at: https://www.fda.gov/medical-devices/safety-communications/fda-recommending-transition-duodenoscopes-innovative-designs-enhance-safety-fda-safety-communication. Accessed May 8, 2020.