DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 7, 2018

Pentax Medical
William Goeller
Vice President, Quality Assurance
and Regulatory Affairs
3 Paragon Drive
Montvale, NJ 07645

Re: K161222
Trade/Device Name: PENTAX MEDICAL ED-3490TK, Video Duodenoscope
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDT
Dated: October 6, 2017
Received: December 21, 2017

Dear William Goeller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161222

Device Name
PENTAX Medical ED-3490TK, Video Duodenoscope

Indications for Use *(Describe)*
The ED-3490TK, Video Duodenoscope, is intended to provide optical visualization (via a video monitor) of, and therapeutic access to the Biliary Tract via the Upper GI Tract. This anatomy includes, but is not restricted to, the organs; tissues; and subsystems: Esophagus, Stomach, Duodenum, Common Bile, Hepatic, and Cystic Ducts. This instrument is introduced via the mouth when indications consistent with the need for procedure are observed in adult and pediatric populations.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter: PENTAX of America, Inc.,
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Date Prepared: January 19, 2018

Trade/Device Name: PENTAX Medical ED-3490TK
Common/Usual Name: Video Duodenoscope
Regulation Number: 21 CFR Part 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDT
Predicate Device: The PENTAX ED-3490TK, Video Duodenoscope (K092710, clearance received on December 2, 2009)

Device Description:

The ED-3490TK Video Duodenoscope must be used with a PENTAX compatible Video Processor (software controlled device). The endoscope has a flexible insertion tube, a control body and umbilicus. The umbilicus provides connection to the video processor. The control body includes controls for up/down/left/right angulation, air/water delivery, suction and an accessory inlet port. The device contains light carrying bundles to illuminate the body cavity and a charge couple device (CCD) to collect image data. The instrument contains a working channel through which biopsy devices or other devices may be introduced. The Video Processor contains a 300 watt short Arc Xenon lamp which provides white light that is focused at the connected video endoscope lightguide prong. The endoscope light carrying bundles present the light to the body cavity and the CCD collects image data. Image data and other screen display information are formatted and presented to the video outputs of the video processor for display.

Intended Use/Indications for Use:

The ED-3490TK, Video Duodenoscope, is intended to provide optical visualization (via a video monitor) of, and therapeutic access to the Biliary Tract via the Upper GI Tract. This anatomy includes, but is not

restricted to, the organs; tissues; and subsystems: Esophagus, Stomach, Duodenum, Common Bile, Hepatic, and Cystic Ducts. This instrument is introduced via the mouth when indications consistent with the need for procedure are observed in adult and pediatric populations.

Summary of Technology Characteristics:

The optical properties and imaging characteristics remain unchanged since the prior submission. The differences between the subject and predicate devices are as follows:

- Distal end design differences (changes in materials and dimensions)
- Modifications to the device's reprocessing procedure and recommendation for annual maintenance.

Safety and Performance Data (Non-clinical tests):

No performance standards or special controls applicable to this device have been adopted under Section 513 or 514 of the Federal Food, Drug, and Cosmetic Act.

PENTAX Medical has conducted performance testing and design analysis to demonstrate the safety and effectiveness of the elevator wire channel seal, as well as the distal end cap seal strength and integrity. No animal or clinical performance testing has been completed.

Biocompatibility:

Biocompatibility of the ED-3490TK was evaluated in accordance with ISO 10993-1.

Software:

Software changes were made to enhance functionality and do not raise new or different questions of safety and effectiveness. Changes were validated in accordance with FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Reprocessing Validation:

Validation of the cleaning, disinfection, and sterilization instructions was performed in accordance with FDA's guidance, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling". The following Technical Information Reports (TIRs) were referenced: AAMI TIR 12:2010, AAMI TIR30:2011.

EMC and Electrical Safety:

No changes have been made to the EMC or electrical safety as compared to prior submission (K092710).

Substantial Equivalence Discussion:

Based on an analysis of the intended use, indications for use, technological characteristics (including fundamental operating principle, energy source, scientific technology, functional characteristics, design features, performance characteristics, and constituent materials), labeling, and sterilization method, we conclude that the subject ED-3490TK Video Duodenoscope is substantially equivalent to

the predicate ED-3490TK Video Duodenoscope (K092710). Labeling and design changes were made to the ED-3490TK that were identified in the bench testing. They have the identical intended use and indications for use. Performance testing and design analysis demonstrate that the ED-3490TK is substantially equivalent to the predicate and the differences raise no new issues of safety or effectiveness

Accordingly, PENTAX Medical believes the ED-3490TK Video Duodenoscope is substantially equivalent to the identified ED-3490TK predicate (K092710).