DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 20, 2017

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

Re: K163614
Trade/Device Name: PENTAX Medical ED34-i10T, Video Duodenoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDT
Dated: August 9, 2017
Received: August 11, 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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
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Office of Device Evaluation
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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)*
K163614

Device Name
PENTAX Medical ED34-i10T Video Duodenoscope

Indications for Use *(Describe)*
The PENTAX Duodenoscope ED34-i10T is intended to provide optical visualization of (via a video monitor), and therapeutic access to, Biliary Tract via the Upper Gastrointestinal Tract. This anatomy includes, but is not restricted to, the organs; tissues; and subsystems: Esophagus, Stomach, Duodenum, Common Bile, Hepatic and Cystic Ducts.
These instruments are introduced via the mouth when indications consistent with the need for the procedure are observed in adult and pediatric patient 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.

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510(k) Summary

Submitter: PENTAX of America, Inc.,
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Date Prepared: September 18, 2017
Trade/Device Name: PENTAX Medical ED34-i10T
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: PENTAX ED-3490TK Video Duodenoscope (K092710, clearance received on December 2, 2009)

Device Description:
The ED34-i10T, Video Duodenoscope is used with a compatible Video Processor.

The ED34-i10T is composed of the following main parts: an insertion portion, control body and PVE connector. The insertion portion is inserted into the body cavity of patient. The insertion portion includes the distal end and bending section. The objective lens, light guide, instrument channel, cannula/forceps elevator, and air/water nozzle are located on the distal end of the insertion portion. The control body is held by the user's hand. The control body includes the angulation control knob, angulation lock knob/lever, cannula/forceps elevator control lever, air/water cylinder, suction cylinder, remote button, and instrument channel inlet. The air/water feeding valve is attached to the air/water cylinder, and the suction control valve is attached to the suction cylinder. The inlet seal is attached to the instrument channel inlet. The PVE connector is connected to the video processor via electrical contacts.

The bending section is bent by the angulation control knob to operate the endoscope angulation. The angulation lock knob/lever is used to adjust the rotation torque of the angulation control knob. The cannula/forceps elevator mechanism is used to control for position of cannula which is inserted through the Instrument Channel.

The cannula/forceps elevator control lever is used to operate the cannula/forceps elevator. The air/water feeding system is used to deliver the air and water to the objective lens from the air/water nozzle. When the hole at the top of air/water feeding valve is covered, the air is delivered. When the air/water feeding valve is pushed, the water is delivered. The suction control system is used to suction the fluid and air in body cavity from the instrument channel. When the suction control valve is pushed, the fluid and air are suctioned.

The remote button is used to operate the function of video processor and external device from the control body,

as necessary.

The detachable and disposable distal cap of ED34-i10T is intended for single use, and is processed with steam sterilization prior to use. It is discarded after use.

Endoscopic devices such as biopsy forceps are inserted from the instrument channel Inlet into the body cavity through the instrument channel.

The light guide of the distal end is used to illuminate the body cavity by light which is carried through the light carrying bundle. The light carrying bundle guides the light from light guide plug which is connected to the light source inside the Video Processor. The CCD built into the distal end receives reflected light (image data) from the body cavity, and sends the image data to the Video Processor through the video cable. The image data are converted into the image signal by the Video Processor, and the image inside the body cavity is displayed on the monitor.

Intended Use/Indications for Use:
"The PENTAX Duodenoscope ED34-i10T is intended to provide optical visualization of (via a video monitor), and therapeutic access to, Biliary Tract via the Upper Gastrointestinal Tract. This anatomy includes, but is not restricted to, the organs; tissues; and subsystems: Esophagus, Stomach, Duodenum, Common Bile, Hepatic and Cystic Ducts.
This endoscope is introduced via the mouth when indications consistent with the need for the procedure are observed in adult and pediatric patient populations."

Summary of Technology Characteristics:
The technological characteristics of the ED34-i10T are functionally equivalent to the predicate device, the ED-3490TK.

While there are some differences in the materials that comprise the distal cap, the air/water channel system, and the control body of the ED-34i10T, those materials that are direct or indirect contact with the human body were assessed for biocompatibility in accordance with ISO 10993-1, 5, and 10: Biological Evaluation of Medical Devices.

The sealed elevator mechanism can be accessed after removal of the single use, detachable and disposable distal cap compared with the permanently fixed cap of ED-3490TK. The detachable and disposable distal cap of ED34-i10T allows the user to access the back side of the elevator for reprocessing.

The ED34-i10T has smaller distance between the control buttons, the shape of the RL knob is changed to from five spokes to six spokes, and the elevator knob surface is wider.

The ED34-i10T has more pixels for optical visualization.

The total overall length of ED34-i10T is slightly shorter than the length of ED-3490TK. As a result of the length reduction, the dimensions of the suction, air and water channels were changed accordingly.

PENTAX has submitted performance testing for the above referenced design differences with this 510(k) that demonstrate that the ED34-i10T is as safe and effective as the predicate device.

Performance Data:

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. The following performance data are provided in support of the substantial equivalence determination.

Detachable Distal Cap

The following performance testing was done for the detachable distal cap: durability, chemical resistance, autoclave, ultrasonic wave cleaning resistance, operating environment, storage environment, thermal shock, and vibration resistance. PENTAX determined that the results of all testing was within the acceptance criteria.

O-Ring Analysis

The O Ring design providing sealing of the Elevator Channel has been analyzed, and a design change created to achieve the recommended minimum compression of 10%.

Optical Testing

Optical properties including signal to noise ratio, spatial resolution (MTF), distortion, light distribution, and spectral distribution were measured for the ED34-i10T in conjunction with the EPK-i5010 video processor. All results show that there are no differences between the subject device, ED34-i10T, and the predicate device, ED-3490TK.

Reprocessing Validation

Simulated use testing, cleaning, high level disinfection, and rinsing (after cleaning and after HLD) validation studies of the ED34-i10T Video Duodenoscope and its detachable and disposable distal cap were conducted and confirmed the effectiveness of reprocessing procedures in accordance with FDA's 2015 Final Guidance, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling ("FDA's 2015 Reprocessing Guidance"). Acceptance criteria were established in accordance with AAMI TIR 30:2011 for amount of residual soil accumulation and extraction efficiency. Acceptance criteria were met after each phase of reprocessing.

Reprocessing and Processing Instructions for Use are provided for the scope and for the single-use detachable distal cap, respectively.

An assessment of the ability of reprocessing staff to carry out the reprocessing instructions (a human factors study for reprocessing instructions) was conducted.

Sterilization and Shelf Life

PENTAX Medical coordinated with STERIS Corporation to validate the use of System 1E liquid chemical sterilization for the sterilization of the ED34-i10T. The device is not provided sterile, therefore, shelf-life is not applicable.

Maintenance

Annual maintenance of the duodenoscope is recommended. This allows PENTAX to inspect the forceps elevator mechanism for wear and required maintenance.

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Biocompatibility

Biocompatibility of direct and indirect contact materials was confirmed by assessing the cytotoxicity, sensitization, and intracutaneous reactivity of the surface device with limited (less than 24 hours) contact with mucosal membrane in accordance with ISO 10993-1, 5, and 10: Biological Evaluation of Medical Devices.

A biocompatibility assessment of the amount of carbon black and titanium oxide contained in the patient contact

parts of the device as well as the tolerable exposure (TE) value was conducted. The risk level of colorant was determined as "Very Low" based on the low concern for toxicity of colorant. The risk level of local toxicity was determined as "Acceptable" as a result of applying the risk level of local toxicity to the risk evaluation criteria.

Software

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software is classified as CLASS B under the Software Safety Classification per IEC 62304:2006, Medical device software- Software life cycle processes) and the software level of concern is "Moderate" based on the FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

EMC and Electrical Safety

The acceptable level of electromagnetic compatibility (EMC) and electrical safety (ES) for the PENTAX ED34-iT10 Video Duodenoscope were confirmed by the following standards: IEC 60601-1-2:2001, A1:2004; IEC 60601 1:2005+CORR 1:2006+CORR 2:2007+AM 1:2012; and IEC 60601-2-18:2009.

Substantial Equivalence Discussion:

After analyzing 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 device ED34-i10T Video Duodenoscope is substantially equivalent to the predicate ED-3490TK Video Duodenoscope. While there are some differences in technological characteristics, the ED-34i10T is as safe and effective as the predicate device and none of the differences raise new questions of safety or effectiveness.