November 15, 2019

PENTAX of America, Inc.
William Goeller
Vice President Quality Assurance and Regulatory Affairs
3 Paragon Drive
Montvale, NJ 07645-1782

Re: K192245
Trade/Device Name: Pentax Medical Video Duodenoscope ED34-i10T2
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDT
Dated: August 16, 2019
Received: August 19, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For:
Shani Haugen, Ph.D.
Acting Assistant Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192245

Device Name
PENTAX Medical Video Duodenoscope ED34-i10T2

Indications for Use *(Describe)*

The PENTAX Medical Video Duodenoscope ED34-i10T2 is intended to be used with endoscopic devices and other ancillary equipment 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.

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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PENTAX Medical Video Duodenoscope ED34-i10T2
Traditional 510(k) Submission

510(k) Summary

I. Submitter:

PENTAX of America, Inc.,
HOYA Corporation PENTAX Division
3 Paragon Drive
Montvale, New Jersey 07645-1782
Phone: 201-571-2318 Ext 2318
Fax: 201-571-2340
Contact: William Goeller
Date Prepared: August 14, 2019

II. DEVICE

The purpose of this 510(k) is to obtain clearance of the PENTAX Medical Video Duodenoscope ED34-i10T2

Table 5.1: Regulatory Classification of PENTAX Medical Video Duodenoscope ED34-i10T2

Device Name	PENTAX Medical Video Duodenoscope ED34-i10T2
Common Name	Video Duodenoscope
Classification Name	Endoscope and accessories
Regulation No.	876.1500
Device Class	2
Product Code	FDT
Classification Panel	Gastroenterology/ Urology

III. PREDICATE DEVICES

The predicate device for this submission, PENTAX Medical ED34-i10T Video Duodenoscope (K163614, K181522), is materially, optically, structurally, mechanically identical to the subject device. The two endoscopes models differ only in their distal tip designs.

Device Description:

The PENTAX Medical Video Duodenoscope ED34-i10T2 is intended to be used with a PENTAX Video Processor, documentation equipment, video monitor, endoscopic device and other ancillary equipment for optical visualization (via a video monitor) of, and/or 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.

The ED34-i10T2 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, elevator link, 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 the position of the cannula which is inserted through the Instrument Channel.

The cannula/forceps elevator control lever is used to operate the cannula/forceps elevator of the Distal End Cap with Elevator (OE-A63). 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 functions of the video processor and any external device from the control body, as necessary.

The single use, Distal End Cap with elevator (OE-A63) is provided as a sterile product. OE-A63 is attached to the elevator link of the distal end of ED34-i10T2. 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.

The PENTAX Medical Video Processors EPK-i5010 and EPK-i7010 are compatible with PENTAX Medical Video Duodenoscope ED34-i10T2.

The primary components of the system include the following:

The PENTAX Medical ED34-i10T2 Video Imaging System is provided with the following accessories:

- Keyboard - input device for the video processor.
- White Balance Adjuster – controls the white balance feature.
- Condenser Earth Cable - used to reduce high-frequency noise generated during high-frequency electro cautery device use with Pentax endoscopes.
- Inlet Seal - prevents suctioned fluid from coming out of the instrument Channel Inlet during the use of suction function. During reprocessing, it seals the instrument Channel Inlet in order to fill the chemical solution inside the channel.
- Bite Block - prevents patients from biting the endoscope insertion tube during an endoscopic examination.
- Suction Control Valve - intended to control suction.
- Air/Water Valve - intended to control air and water feeding.
- Distal End Cap with Elevator - intended to guide the endoscopic device.

Additional accessories for reprocessing are provided with the device. These include a Cleaning Adapter, Soaking Cap, Ventilation Cap, Endoscope Cleaning Brush Kits, and replacement O- Rings.

V. INDICATIONS FOR USE

The PENTAX Medical Video Duodenoscope ED34-i10T2 is intended to be used with endoscopic devices and other ancillary equipment 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.

VI. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE

The components of the PENTAX Medical ED34-i10T2 Video Duodenoscope has the same fundamental technology and operating principles as the predicate device, as well as the same intended use. Both the PENTAX Medical Video Duodenoscope ED34-i10T2 and the predicate devices are intended for illuminating and viewing the inside of the human body.

The components of the PENTAX Medical Video Duodenoscope ED34-i10T2 consist of the same components as the predicate device, including:

- A video processor,
- Video Duodenoscope to provide optical visualization of (via a video monitor), and therapeutic access to, Biliary Tract via the Upper Gastrointestinal Tract.
- Accessories, including but not limited to a keyboard, foot switch, White Balance Adjuster, and Condenser Earth Cable

The subject and predicate devices are identical with regard to

- Scope working length
- Scope field of view
- Scope depth of field
- Scope tip angulation
- Software requirements

The patient contacting components of both the subject and predicate devices are biocompatible. Both subject and the predicate scopes are reprocessed by the user except the Distal End Cap with Elevator (OE-A63) of ED34-i10T2 which is provided as a single-use, sterile product.

The technological differences between the subject and predicate devices include:

- Difference in materials, structure and in particular the provision method of the distal end including elevator section:

  Single-use, sterile Distal End Cap with Elevator is attached at distal end section of ED34-i10T2,

  Single-use, non-sterile Distal End Cap is attached at the distal end section of the ED34-i10T (predicate) where the permanent elevator section is located.

- Difference in structure of the distal end between the subject device and predicate device:

  The elevator section of ED34-i10T2 does not exist at the distal end portion of the subject device. Instead, a small stainless steel bar is located at the distal tip to connect the Distal End Cap with Elevator and to operate the elevator located in the cavity of the Distal End Cap with Elevator.

  ED34-i10T (predicate) has a permanent elevator made of stainless steel at the distal end of the device.

  The removal of the single use, sterile Distal End Cap with Elevator (OE-A63) of ED34-i10T2 allows the user to access all surfaces of the distal end area where patient fluid may be accumulated.

VII. PERFORMANCE DATA

The following performance data are provided to support the equivalence of the subject and predicate devices.

a. Reprocessing Validation

An engineering assessment was made to determine whether the existing data generated from reprocessing validation study of ED34-i10T can be applied to support ED34-i10T2.

As result of the assessment, simulated use testing, cleaning and rinsing (after cleaning and after HLD) validation studies were conducted at all of evaluation sites, and high level disinfection was conducted at the distal end of the ED34-i10T2 Video Duodenoscope ,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.

All acceptance criteria were satisfied.

b. ***O-Ring Analysis***

O-Ring Compression Ratio

PENTAX Medical submitted a special 510(k) for the design change in the dimensions of the O-ring and the elevator link of the predicate device ED34-i10T. The design change has been cleared on July 9, 2018 (K181522).

The materials and dimensions which may impact the O-ring compression are identical between the subject device ED34-i10T2 and the predicate device ED34-i10T.

Through analysis, the modification has demonstrated a Compression Ratio that met the pre-determined acceptance criterion.

c. 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-i10T2. The device is not provided sterile, therefore, shelf-life is not applicable.

The Distal End Cap with Elevator (OE-A63) is provided as a single-use, sterile product. The following verification studies were performed to support labeling the product with a shelf-life of two years.

- Establishing the maximum acceptable dose

- Product performance qualification
- Packing performance qualification
- Product safety qualification
- Establishing the sterilization doze
- IQ, OQ, PQ of the sterilizer

The irradiated products were tested to verify that they meet their design specifications after irradiation at the maximum acceptable dose (60kGy or more) at each of the following storage times: (i) immediately after irradiation, (ii) after 6 months, (iii) after 2 years (accelerated aging).

All acceptance criteria were satisfied.

PENTAX Medical plans to test the product again after real time storage of three years or more.

d. Biocompatibility

Biocompatibility of the ED34-i10T2 scope on direct and indirect contact materials, and of the Distal End Cap with Elevator (OE-A63) accelerated aging for 2-years or more after irradiation of the maximum acceptable dose (60kGy or more) were respectively 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. Biocompatibility assessments of the amount of carbon black and titanium oxide contained in the patient contact parts of both devices as well as the tolerable exposure (TE) value were conducted. The risk levels of colorant on both devices were respectively determined as "Very Low" based on the low concern for toxicity of colorant. The risk levels of local toxicity were respectively determined as "Acceptable" as a result of applying the risk level of local toxicity to the risk evaluation criteria.

It is concluded that the biological risks of both ED34-i10T2 and Distal End Cap with Elevator (OE-A63) are acceptable based on the test results.

e. Software

The subject devices utilize the same software as the predicate device.

f. Electrical Safety and Electromagnetic Compatibility (EMC)

PENTAX Medical ED34-i10T2 and compatible PENTAX Video Processors including EPK-i5010 and EPK-i7010 were tested for electromagnetic compatibility (EMC) and electrical safety (ES).
The scope was tested in accordance with the following standards and passed all testing:

- IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012
- IEC 60601-2-18:2009
- IEC 60601-1-2:2014 (4th edition)

g. Optical testing

All items that affect optical performance for subject device ED34-i10T2 are identical with the predicate device ED34-i10T.

h. Distal End Cap with Elevator, OE-A63 Performance Testing

Verification studies including attachment performance tests were conducted on the Distal End Cap with Elevator, OE-A63, all test items satisfied the acceptance criteria and were determined to be acceptable.

i. Human Factors Testing

PENTAX Medical conducted a Supplemental Summative Human Factors Study to validate the effectiveness and the risk management measures that are in place for the reprocessing of the ED34-i10T2 Video Duodenoscope. The study examined if the RIFU (reprocessing instructions for use) would be used without serious errors or problems for the intended uses under expected conditions.

VIII. CONCLUSION

The ED34-i10T2 is designed with a Disposable Elevator Cap to help simplify duodenoscope reprocessing and to help reduce duodenoscope contamination.

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, PENTAX Medical concludes that the subject ED34-i10T2 Video Duodenoscope is substantially equivalent to the predicate device ED34-i10T.