April 9, 2021

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

Re: K210710
Trade/Device Name: PENTAX Medical Video Duodenoscope ED34-i10T2
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDT
Dated: March 7, 2021
Received: March 10, 2021

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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
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)*
K210710

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
Special 510(k) Submission

510(k) Summary

I. Submitter:

PENTAX of America, Inc.,
HOYA Corporation PENTAX Division
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Montvale, New Jersey 07645-1782
Phone: 201-571-2318 Ext 2318
Fax: 201-571-2340
Contact: William Goeller
Date Prepared: March 31, 2021

II. DEVICE

The purpose of this special 510(k) is to get clearance to the updated instructions that enhance awareness of Distal End Cap attachment process.

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-i10T2 Video Duodenoscope (K192245), is materially, optically, structurally, mechanically identical to the subject device.

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.

IV. 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.

V. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE

PENTAX Medical ED34-i10T2 Video Duodenoscope has the same Intended use, fundamental technology, operating principles, components and materials as the predicate device.

The only differences between the subject and predicate devices include:

- The updated instructions that enhance awareness of Distal End Cap attachment process.
- The following minor change has been applied to the subject software: Two different software versions are installed in PENTAX Medical Video Duodenoscope ED34-i10T2, dependent on the manufacturing timing. These two software versions are released due to the obsolescence of electronic components used for the endoscope. Functions realized by these two software are identical, and the difference of the software versions does not affect safety or effectiveness for the device, or any hardware performance such as CPU processing speed.

VI. PERFORMANCE DATA

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

a. Software and Cybersecurity

A minor change was applied to ED34-i10T2 software. Two different software versions are installed in PENTAX Medical Video Duodenoscope ED34-i10T2, dependent on the manufacturing timing. Functions realized by these two software are identical, and the difference of the software versions does not affect safety or effectiveness for the device, or any hardware performance such as CPU processing speed.

Software verification and validation including cybersecurity assessments were conducted according to IEC 62304: 2006 + A1: 2015 and FDA Guidances for Industry and Staff "*Guidance for the Content of Premarket Submissions forSoftware Contained in Medical Devices.*", "*Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*" and "*Postmarket Management of Cybersecurity in Medical Devices.*"

VII. CONCLUSION

PENTAX Medical concluded that the PENTAX Medical ED34-i10T2 is substantially equivalent to the predicate device ED34-i10T2 cleared in K192245.