April 1, 2021

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

Re: K202365
Trade/Device Name: Pentax Medical Video Duodenoscope ED32-i10
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDT
Dated: August 14, 2020
Received: August 19, 2020

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, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202365

Device Name
PENTAX Medical Video Duodenoscope ED32-i10

Indications for Use *(Describe)*
The PENTAX Medical Video Duodenoscope ED32-i10 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.

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

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K202365
PENTAX Medical Video Duodenoscope ED32-i10
510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 221 CFR 807.92. All data included in this document is accurate and complete to the best of PENTAX Medical's knowledge.

I. SUBMITTER

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Date Prepared: 8/14/2020

II. DEVICE

The regulatory classification of PENTAX Medical Video Duodenoscope ED32-i10 is identified in Table 5.1.

Table 5.1. Regulatory Classification of PENTAX Medical Video Duodenoscope ED32-i10

Name of the System	PENTAX Medical Video Duodenoscope ED32-i10
Common Name	Video Duodenoscope
Regulation Number	876.1500
Regulation Names	Endoscope and accessories
Regulatory Class	Class II
Product Code	FDT
Classification Panel	Gastroenterology/ Urology

III. PREDICATE DEVICE

The predicate device for this submission, PENTAX Medical Video Duodenoscope ED34-i10T2 (K192245) is materially, structurally and mechanically identical to the subject device and has an identical optical design except the direction of view. The two endoscopes models differ mainly in their insertion portion dimensions.

Predicate Device: PENTAX Medical Video Duodenoscope ED34-i10T2 (K192245)

PENTAX Medical is seeking clearance of a new product of Video Duodenoscope ED32-i10 with the compatible PENTAX Video Processors EPK-i5010 (K122470) and EPK-i7010 with GI Family (K150618). This 510(k) also captures some minor design changes that have occurred during the evolution of the product line. Although the changes are believed to be minor, the 510(k) is being submitted to account for technological advances in associated compatible devices and to ensure that FDA has the most current information concerning the PENTAX Medical Video Duodenoscope ED32-i10.

The subject devices have virtually the same indications for use, viewing directions, and image size as the predicates. The subject device uses the same processors and peripherals as the predicate device.

The main differences between the subject devices and predicate devices are as follows:

- Introduction of a new line of Video Duodenoscope ED32-i10 as compatible Video Duodenoscope ED34-i10T2.
- The single use, sterile Distal End Cap with Elevator OE-A65 for the ED32-i10 has same mechanical constructions as another distal end cap OE-A63 for the ED34-i102, with the smaller width due to narrower insertion portion width.

IV. DEVICE DESCRIPTION

The PENTAX Medical Video Duodenoscope ED32-i10 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 PENTAX Medical Video Duodenoscope ED32-i10 has a smaller insertion portion width (32 French size) compared to the predicate device, ED34-i10T2, (34 French size) and is expected to provide better access to patients for whom that the ED34-i10T2 may have had difficulties accessing, for example in patients with narrowed lumens and in pediatric patients.

The ED32-i10 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-A65). 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-A65) is provided as a sterile product. OE-A65 is attached to the elevator link of the distal end of ED32-i10. 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 ED32-i10.

The PENTAX Medical ED32-i10 Video Imaging System is provided with the following accessories:

- 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 ED32-i10 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. COMPATIBLE VIDEO PROCESSORS

The PENTAX Medical Video Duodenoscope ED32-i10 is compatible with PENTAX Medical video processors EPK-i5010 and EPK-i7010, previously cleared with other PENTAX Medical GI scopes K122470 and K150618, respectively.

VII. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE

The PENTAX Medical Video Duodenoscope ED32-i10 is functionally equivalent to the predicate devices, the PENTAX Medical Video Duodenoscope ED34-i10T2 (K192245). The only difference between the two devices are minor technological changes.

The changes in the subject device has been evaluated through performance testing and raise no issue of safety and effectiveness of the device as these differences have no effect on the performance, function or general intended use of the device.

The components of the PENTAX Medical Video Duodenoscope ED32-i10 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 ED32-i10 and the predicate device are intended for illuminating and viewing the inside of the human body. The components of the PENTAX Medical Video Duodenoscope ED32-i10 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 materials of both the subject and predicate devices are identical and biocompatible. Both subject and the predicate scopes are reprocessed by the user except the Distal End Cap with Elevator (OE-A65) of ED32-i10 which is provided as a single-use, sterile product. The removal of the single use, sterile Distal End Cap with Elevator (OE-A65) of ED32-i10 allows the user to access all surfaces of the distal end area where patient fluid may be accumulated.

VIII. NON-CLINICAL PERFORMANCE DATA

The PENTAX Medical Video Duodenoscope ED32-i10 has been successfully tested for their functions, performance and safety as per FDA recognized consensus standards. The following performance data are provided in support of the substantial equivalence determination.

Operational and Reprocessing Instructions for Use are provided for the scope.

a. *Reprocessing Validation*
As result of the assessment, simulated use testing, cleaning, high level disinfecting and rinsing (after cleaning and after HLD) validation studies were conducted at the distal end, instrument/suction channel, and air/water channel of the ED32-i10 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. *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 ED32-i10. The device is not provided sterile, therefore, shelf-life is not applicable.

The Distal End Cap with Elevator (OE-A65) is provided as a single-use, sterile product. Electron beam sterilization was conducted and a shelf-life of 2 years after sterilization was verified.

c. *O-ring Sealing Performance*
The O-ring located on the elevator link has the same dimensions and sealing performance as the predicate device.

d. *Software*
The subject device utilizes the same software as the predicate device.

e. *EMC and Electrical Safety*
The acceptable level of electromagnetic compatibility (EMC) and electrical safety (ES) for the PENTAX Medical Video Duodenoscope ED32-i10 were confirmed by the following standards:
IEC 60601-1-2:2014; IEC 60601- 1:2005+CORR 1:2006+CORR 2:2007+A1:2012; and IEC 60601-2-18:2009.

f. *System Performance*
The system performance of the subject device demonstrated the equivalence to the predicate device. Test results also demonstrated six years of the service life for the ED32-i10.

g. *Optical Performance*

As a part of Design Verification and Validation, optical properties including signal to noise, color, limiting spatial resolution (LSR), modulation transfer function (MTF), distortion, image intensity uniformity (IIU) and photobiological safety were measured for the ED32-i10 in conjunction with the EPK-i7010 and EPK-i5010 Video Processors. All results show that the optical characteristics of the subject device is equivalent to those of the predicate device.

h. *Distal End Cap with Elevator, OE-A65 Performance Testing*

Verification studies including attachment performance tests were conducted on the Distal End Cap with Elevator, OE-A65, all test items satisfied the acceptance criteria and were determined to be acceptable.

i. *Human Factors Testing*

The proposed manual reprocessing procedures of subject device ED32-i10 are identical with those of predicate device ED34-i10T2 (K192245), except the nomenclature of the distal end cap with elevator. Also, all critical tasks of ED32-i10 are identical to the critical tasks of ED34-i10T2, and the user-interface is the same between ED32-i10 and ED34-i10T2. Therefore, Human Factors validation testing from the ED34-i10T2 was leveraged for the ED32-i10.

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 PENTAX Medical Video Duodenoscope ED32-i10 is as safe and effective as the predicate device. There are no differences in indications for use and intended use between the subject and predicate device and are therefore, substantially equivalent. The technological differences in terms of design features, performance characteristics and constituent materials are not substantive.

IX. CONCLUSION

Accordingly, PENTAX Medical believes the PENTAX Medical Video Duodenoscope ED32-i10 is substantially equivalent to the identified predicate, the PENTAX Medical Video Duodenoscope ED34-i10T2, cleared by FDA in 2019 (K192245).