August 1, 2024

Pentax of America, Inc.
Gurvinder Singh Nanda
Senior Director, Regulatory and Quality
3 Paragon Drive
Montvale, New Jersey 07645

Re: K233942
Trade/Device Name: PENTAX Medical Video Duodenoscope (ED34-i10T2s); PENTAX Medical Video Processor (EPK-i8020c); PENTAX Medical Single Use, Sterile Distal End Cap with Elevator (OE-A63); Gas/Water Feeding Valves (OF-B194)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDT, FET
Dated: July 5, 2024
Received: July 5, 2024

Dear Gurvinder Singh Nanda:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233942

Device Name

PENTAX Medical Video Duodenoscope (ED34-i10T2s);
PENTAX Medical Video Processor (EPK-i8020c);
PENTAX Medical Single Use, Sterile Distal End Cap with Elevator (OE-A63);
Gas/Water Feeding Valves (OF-B194)

Indications for Use *(Describe)*

PENTAX Medical Video Duodenoscope ED34-i10T2s
The PENTAX Medical Video Duodenoscope ED34-i10T2s 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 the biliary tract via the upper gastrointestinal tract. This anatomy includes the organs; tissues; and subsystems of the: esophagus, stomach, duodenum, common bile duct, hepatic ducts, cystic duct, and pancreatic duct.
This endoscope is introduced via the mouth when indications consistent with the need for the procedure are observed in adult and pediatric patient populations.

PENTAX Gas/Water Feeding Valve OF-B194
Gas/water feeding valve is attached in place of air/water feeding valve to the gastrointestinal endoscope, in order to prevent the leaking of the nonflammable gas into the room, and feed the gas or water into the gastrointestinal tract or abdominal cavity. It also prevents back flow/splashing of body fluids.

PENTAX Medical Video Processor EPK-i8020c
The PENTAX Medical Video Processor EPK-i8020c is intended to be used with the PENTAX Medical camera heads, endoscopes, light sources, monitors and other ancillary equipment for gastrointestinal and pulmonary endoscopic diagnosis, treatment and video observation.
The PENTAX Medical EPK-i8020c includes a digital post-processing imaging enhancement technology (PENTAX i-ScanTM), and optical imaging enhancement technology (OE). These imaging enhancement technologies are intended to be used as an optional adjunct following traditional white light endoscopy and is not intended to replace histopathological sampling. i-Scan and OE are compatible with PENTAX Medical video gastrointestinal endoscopes and bronchoscopes.

PENTAX Medical Single Use, Sterile Distal End Cap with Elevator OE-A63
The PENTAX Medical Single Use, Sterile Distal End Cap with Elevator OE-A63 fully integrates a movable elevator, whose function it is to guide endoscopic devices. The OE-A63 is controlled by the PENTAX Medical Video Duodenoscopes and is necessary to meet the intended use of the duodenoscope.

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.

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.

1. SUBMITTER

Applicant: PENTAX of America, Inc.
HOYA Corporation PENTAX Division
3 Paragon Drive
Montvale, New Jersey 07645-1782

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Date Prepared: 12-13-2023

2. SUBJECT DEVICE

PENTAX Medical is seeking clearance of a new product of PENTAX Medical Video Duodenoscope ED34-i10T2s with the compatible PENTAX Medical Video Processors EPK-i8020c, and PENTAX Medical Single Use, Sterile Distal End Cap with Elevator OE-A63.

Device Name	PENTAX Medical Video Duodenoscope ED34-i10T2s, PENTAX Medical Video Processor (EPK-i8020c); PENTAX Medical Single Use, Sterile Distal End Cap with Elevator (OE-A63); Gas/Water Feeding Valves (OF-B194)
Common Name	Video Duodenoscope
Classification Name	Endoscope and accessories
Regulation No.	876.1500
Device Class	II
Product Code	FDT, FET
Classification Panel	Gastroenterology/ Urology

3. PREDICATE DEVICE

A previously cleared PENTAX Medical Video Duodenoscope ED34-i10T2 (K192245) has been chosen as a predicate device and a recently cleared version of the EPK-i8020c as the secondary predicate device (K232860)

4. DEVICE DESCRIPTION

PENTAX Medical Video Duodenoscope ED34-i10T2s is designed to be used with a PENTAX Medical Video Processor, documentation equipment, video monitor, endoscopic devices such as biopsy forceps and other ancillary equipment for optical visualization (via a video monitor) of, and/or therapeutic access to the biliary tract via the upper gastrointestinal tract. The PENTAX Medical Video Duodenoscope ED34-i10T2s is compatible with the hydrogen peroxide gas plasma sterilizer STERRAD 100NX.

5. INTENDED USE AND INDICATIONS FOR USE

PENTAX Medical Video Duodenoscope ED34-i10T2s

The PENTAX Medical Video Duodenoscope ED34-i10T2s 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 the biliary tract via the upper gastrointestinal tract. This anatomy includes the organs; tissues; and subsystems of the: esophagus, stomach, duodenum, common bile duct, hepatic ducts, cystic duct, and pancreatic duct. This endoscope is introduced via the mouth when indications consistent with the need for the procedure are observed in adult and pediatric patient populations.

Indications for Use for the PENTAX Gas/Water Feeding Valve OF-B194

Gas/water feeding valve is attached in place of air/water feeding valve to the gastrointestinal endoscope, in order to prevent the leaking of the nonflammable gas into the room, and feed the gas or water into the gastrointestinal tract or abdominal cavity. It also prevents back flow/splashing of body fluids.

Indications for Use for the PENTAX Medical Video Processor EPK-i8020c

The PENTAX Medical Video Processor EPK-i8020c is intended to be used with the PENTAX Medical camera heads, endoscopes, light sources, monitors and other ancillary equipment for gastrointestinal and pulmonary endoscopic diagnosis, treatment and video observation.

The PENTAX Medical EPK-i8020c includes a digital post-processing imaging enhancement technology (PENTAX i-ScanTM), and optical imaging enhancement technology (OE). These imaging enhancement technologies are intended to be used as an optional adjunct following traditional white light endoscopy and is not intended to replace

histopathological sampling. i-Scan and OE are compatible with PENTAX Medical video gastrointestinal endoscopes and bronchoscopes.

PENTAX Medical Single Use, Sterile Distal End Cap with Elevator OE-A63

The PENTAX Medical Single Use, Sterile Distal End Cap with Elevator OE-A63 fully integrates a movable elevator, whose function it is to guide endoscopic devices. The OE-A63 is controlled by the PENTAX Medical Video Duodenoscopes and is necessary to meet the intended use of the duodenoscope.

6. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE

The subject device is functionally equivalent to the predicate device, and the difference between the two devices are minor technological changes such as the compatibility with the Hydrogen peroxide gas plasma sterilizer STERRAD 100NX.

The changes in the subject device have been evaluated through performance testing and raised no issues of safety and effectiveness of the device. These differences have no effect on the performance, function or general intended use of the device.

The components of the subject device have the same fundamental technology and principle of operation as the predicate device. Both the subject device and the predicate device are intended for illuminating and viewing the inside of the human body. The components of the subject device 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 (with EPK-i7010 and EPK-i5010 only)

The subject device is identical or enhanced to the predicate device with regards to;

- Working length
- Field of view
- Depth of field
- Tip angulation
- Rigid distal width
- Insertion tube width
- Maximum insertion portion width

- Maximum instrument channel width
- Software requirements

Following changes have also been implemented to the existing PENTAX Medical accessories:

- The Instructions for Use for PENTAX Gas/Water Feeding Valve OF-B194 has been updated to provide users with detailed reprocessing procedures.
- The Intended Use/Indications for Use of PENTAX Medical Single-use, Sterile Distal End Cap with Elevator OE-A63 has been modified so that the accessory is compatible with the subject device (ED34-i10T2s) as well as the predicate device (ED34-i10T2).

7. NON-CLINICAL PERFORMANCE DATA

PENTAX Medical Video Duodenoscope ED34-i10T2s 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.

i. Reprocessing Validation

As result of the assessment, simulated use testing, cleaning, high level disinfecting and rinsing (after cleaning and after HLD) validation studies of the ED34-i10T2s 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."* 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.

ii. Sterilization and Shelf Life

PENTAX Medical coordinated with STERIS Corporation to validate the use of System 1E and 1 endo liquid chemical sterilization for the sterilization of the ED34- i10T2s, and also coordinated with Advanced Sterilization Products, Inc. to validate the use of STERRAD 100NX hydrogen peroxide gas plasma sterilization for the sterilization of the ED34-i10T2s. 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. However, no testing of sterilization and shelf life require since the change has been applied to the labeling only.

iii. Biocompatibility

Biocompatibility of the ED34-i10T2s duodenoscope on the direct and indirect contact materials was confirmed by assessing the cytotoxicity, sensitization, and intracutaneous reactivity in accordance with ISO 10993-1: 2018 "*Biological evaluation of medical devices"*. The risk levels of local toxicity were determined as "Acceptable" as a result of applying the risk level of local toxicity to the risk evaluation criteria.

iv. Software and Cybersecurity

PENTAX Medical Video Processor (EPK-i8020c) had a software update relative to the original submission (K232860) to add compatibility with the ED34-i10T2s duodenoscope and fix bugs. Software verification and validation including cybersecurity assessments were conducted according to IEC 62304: 2006 + A1: 2015 and FDA Guidance for Industry and Staff *"Content of Premarket Submissions for Device Software Functions", "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions",* and *"Postmarket Management of Cybersecurity in Medical Devices".*

v. Electrical Safety and EMC

EMC and Electrical safety testing were successfully conducted per the new standards IEC60601-1-2 Edition 4.0:2014-02; ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012 C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text); and IEC 60601-2-18 Edition 3.0:2009-08 and recent EMC guidance.

vi. System Performance

The system performance of the subject device demonstrated the equivalence to the predicate device.

vii. Optical Performance

No testing of optical characteristics was performed for the ED34-i10T2s since the subject device has the same optical designs as the predicate device.
Details are described in the "Performance Testing" section.

viii. Human Factors Testing

The Human Factors study results of the predicate K192245 were leveraged and additional supplemental usability testing was successfully conducted to support human factors validation of the ED34-i10T2s. Details are described in the "Performance Testing" section.

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, PENTAX Medical concludes that the subject device is as safe and effective as the predicate devices. 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.

8. CONCLUSION

PENTAX Medical Video Duodenoscope ED34-i10T2s does not raise any different questions of safety and effectiveness. The subject device PENTAX Medical Video Duodenoscope ED34-i10T2s with the compatible PENTAX Medical Video Processors EPK-i8020c, and PENTAX Medical Single Use, Sterile Distal End Cap with Elevator OE-A63 is substantially equivalent to the identified predicates, the PENTAX Medical Video Duodenoscope ED34-i10T2 cleared by FDA in K192245 and as the secondary predicate device (K232860).