January 3, 2025

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

Re: K242110
Trade/Device Name: PENTAX Medical Video Colonoscope (EC38-i20cWL)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDF
Dated: December 5, 2024
Received: December 6, 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242110

Device Name

PENTAX Medical Video Colonoscope (EC38-i20cWL)

Indications for Use *(Describe)*

The PENTAX Medical Video Colonoscope EC38-i20cWL is intended to provide optical visualization of (via a video monitor), and therapeutic access to, the lower gastrointestinal tract. This anatomy includes the organs, tissues, and subsystems: Large Bowel to the cecum, terminal ileum of the small bowel.

This endoscope is introduced via the rectum, as decided by the physician, when indications consistent with the need for the procedure are observed in patient populations with greater than 20kg of body weight.

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.

PENTAX Medical Video Colonoscope EC38-i20cWL
Traditional 510(k) Submission

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 21 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 Medical
HOYA Corporation PENTAX Division
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Montvale, New Jersey 07645-1782

Contact: Gurvinder Singh Nanda, PhD
Sr. Director, Regulatory and Quality
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Date Prepared: 07/18/2024

2. SUBJECT DEVICE

PENTAX Medical is seeking clearance of new products, PENTAX Medical Video Colonoscope EC38-i20cWL.

Device Name	PENTAX Medical Video Colonoscope EC38-i20cWL
Common Name	Gastroscope and Accessories, Flexible/Rigid
Classification Name	Endoscope and accessories
Regulation No.	876.1500
Device Class	II
Product Code	FDF
Classification Panel	Gastroenterology / Urology

3. PREDICATE DEVICE and REFERENCE DEVICE

Previously cleared PENTAX Medical Video Scopes have been chosen as predicate device and reference device:

Subject Device	Predicate Device	Reference Device
PENTAX Medical Video Colonoscope EC38-i20cWL	PENTAX Video Colonoscope EC38-i10L (K131855)	PENTAX Medical Video Colonoscope EC38-i20cL (K231249)

4. DEVICE DESCRIPTION

PENTAX Medical Video Colonoscope EC38-i20cWL

The PENTAX Medical Video Colonoscope EC38-i20cWL is designed to be used with a PENTAX Medical Video Processor, 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 lower digestive tract.

5. INTENDED USE AND INDICATIONS FOR USE

Intended use and Indications for use for PENTAX Medical Video Colonoscope EC38-i20cWL

The PENTAX Medical Video Colonoscope EC38-i20cWL is intended to provide optical visualization of (via a video monitor), and therapeutic access to, the lower gastrointestinal tract. This anatomy includes the organs, tissues, and subsystems: Large Bowel to the cecum, terminal ileum of the small bowel.

This endoscope is introduced via the rectum, as decided by the physician, when indications consistent with the need for the procedure are observed in patient populations with greater than 20kg of body weight.

6. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE/REFERENCE DEVICES

The subject device is functionally equivalent to the predicate/reference devices, and the differences between the devices are minor technological changes such as the application of wide field of view for the new endoscope. There is no new technological feature in the subject device in comparison to the reference device, K231249.

The change made to the subject device have been evaluated by successful performance testing with no safety or effectiveness concerns raised. These differences have no impact on the overall performance, functionality, or intended use of the devices.

The components of the subject device have the same fundamental technology and principle of operation as the predicate/reference devices. Both the subject device and the predicate device are intended for illuminating and viewing the inside of the human body.

The subject device are identical or enhanced to the predicate/reference devices with regards to;

- Scope working length
- Scope field of view
- Scope depth of field
- Scope tip angulation
- Rigid distal width
- Insertion tube width
- Maximum insertion portion width
- Minimum instrument channel width
- Software requirements

7. NON-CLINICAL PERFORMANCE DATA

The subject device have 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 EC38-i20cWL 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 liquid chemical sterilization for the sterilization of the EC38-i20cWL.

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

iii. Biocompatibility

The biocompatibility of EC38-i20cWL 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

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

The acceptable level of electrical safety (ES) and electromagnetic compatibility (EMC) were confirmed by the following standards:
IEC 60601-1-2:2014 + A1:2020; IEC 60601-1:2005 + A1:2012 + A2:2020; IEC 60601-1-6:2010 + A1:2013 +A2:2020; and IEC 60601-2-18:2009.

vi. System Performance

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

vii. Optical Performance

As a part of Design Verification and Validation, optical properties of imaging and illumination performances were measured for the subject device. All results show that the optical characteristics of the subject device are equivalent to those of the predicate device.

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/reference devices. There are no differences in indications for use and intended use between the subject and predicate/reference devices and are therefore, substantially equivalent. The technological differences in terms of design features, performance characteristics and constituent materials are not significant.

8. CONCLUSION

The PENTAX Medical Video Colonoscope EC38-i20cWL does not pose any unique questions regarding safety and effectiveness. It is deemed to be substantially equivalent to the identified predicates: the PENTAX Video Colonoscope EC38-i10L (K131855).