December 16, 2025

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

Re: K251256
Trade/Device Name: PENTAX Medical Video Upper GI Scopes (EG Family) (EG Family); PENTAX Medical Video Colonoscopes (EC Family) (EC Family)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDS, FDF
Dated: November 14, 2025
Received: November 14, 2025

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,

SIVAKAMI VENKATACHALAM -S

*for*
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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K251256 |

Please provide the device trade name(s).

PENTAX Medical Video Upper GI Scopes (EG Family) (EG Family);
PENTAX Medical Video Colonoscopes (EC Family) (EC Family)

Please provide your Indications for Use below.

PENTAX Medical Video Upper GI Scopes (EG Family):
This instrument is intended to be used with a PENTAX video processor (including light source), documentation equipment, monitor, Endotherapy Device such as a Biopsy Forceps, and other ancillary equipment for endoscopy and endoscopic surgery within the upper digestive tract including the esophagus, stomach, and duodenum.

PENTAX Medical Video Colonoscopes (EC Family):
This instrument is intended to be used with a PENTAX Video Processor (including light source), documentation equipment, Monitor, Endotherapy Device such as a Biopsy Forceps, and other ancillary equipment for endoscopy and endoscopic surgery within the lower digestive tract including the anus, rectum, sigmoid colon, colon and ileocecal valve.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

## 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 Medical
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Montvale, New Jersey 07645-1782

**Contact:** Gurvinder Singh Nanda, PhD
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**Date Prepared:** 04/22/2025

### 2. SUBJECT DEVICE and PREDICATE DEVICE

PENTAX Medical is seeking clearance of PENTAX Medical Video Upper GI Scopes (EG Family) and PENTAX Medical Video Colonoscopes (EC Family). Table 1 provides the regulatory information for the subject devices.

*Table 1. Regulatory Information for the Subject Devices*

| | | |
|---|---|---|
| **Device Name** | PENTAX Medical Video Upper GI Scopes (EG Family) | PENTAX Medical Video Colonoscopes (EC Family) |
| **Common Name** | Gastroscope And Accessories, Flexible/Rigid | Colonoscope And Accessories, Flexible/Rigid |
| **Classification Name** | Endoscope and accessories | |
| **Regulation No.** | 876.1500 | |
| **Device Class** | II | |
| **Product Code** | FDS | FDF |
| **Classification Panel** | Gastroenterology / Urology | |

Previously cleared PENTAX Medical Video Scopes have been selected as predicate devices, as shown in Table 2 below. The specific model names of the subject devices are listed in Table 3.

*Table 2. Subject Devices and Predicate Devices*

| Subject Device | Predicate Device |
|---|---|
| PENTAX Medical Video Upper GI Scopes (EG Family) | PENTAX Medical Video Upper GI Scopes (EG Family) (K131902) |
| PENTAX Medical Video Colonoscopes (EC Family) | PENTAX Medical Video Colonoscopes (EC Family) (K131855) |

*Table 3. Specific Model Names of Subject Devices*

| | |
|---|---|
| PENTAX Medical Video Upper GI Scopes (EG Family) | EG-2490K |
| | EG27-i10 |
| | EG-2990i |
| | EG29-i10 |
| | EG-3890TK |
| PENTAX Medical Video Colonoscopes (EC Family) | EC-2990Li |
| | EC-3890Li |
| | EC-3890TLK |
| | EC34-i10L |
| | EC38-i10L |

## 3. DEVICE DESCRIPTION

**PENTAX Medical Video Upper GI Scopes (EG Family)**

These instruments are intended to be used with a PENTAX video processor (including light source), documentation equipment, Monitor, Endotherapy Device such as a Biopsy Forceps, and other ancillary equipment for endoscopy and endoscopic surgery within the upper digestive tract including the esophagus, stomach, and duodenum.

**PENTAX Medical Video Colonoscopes (EC Family)**

These instruments are intended to be used with a PENTAX video processor (including light source), documentation equipment, Monitor, Endotherapy Device such as a Biopsy Forceps, and other ancillary equipment for endoscopy and endoscopic surgery within the lower digestive tract including the anus, rectum, sigmoid colon, colon and ileocecal valve.

## 4. INTENDED USE AND INDICATIONS FOR USE

**Intended use and Indications for use for PENTAX Medical Video Upper GI Scopes (EG Family)**

This instrument is intended to be used with a PENTAX video processor (including light source), documentation equipment, monitor, Endotherapy Device such as a Biopsy Forceps, and other ancillary equipment for endoscopy and endoscopic surgery within the upper digestive tract including the esophagus, stomach, and duodenum.

**Intended use and Indications for use for PENTAX Medical Video Colonoscopes (EC Family)**

This instrument is intended to be used with a PENTAX Video Processor (including light source), documentation equipment, Monitor, Endotherapy Device such as a Biopsy Forceps, and other ancillary equipment for endoscopy and endoscopic surgery within the lower digestive tract including the anus, rectum, sigmoid colon, colon and ileocecal valve.

## 5. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE/REFERENCE DEVICES

The subject devices are identical to the predicate devices. The subject devices have the same fundamental technology and operating principles of the predicate devices, including the same intended use and designs, such as Insertion Portion, Control Body and fiberoptic illumination. There are no differences in specifications, including, but not limited to, the depth of field, distal end width, insertion tube width, instrument channel width, and total length.

The changes between the subject and predicate devices are limited to labeling updates, change in Reprocessing procedure, mechanical modifications for compliance with IEC 60601-1-2, and patient-contact material changes. The changes made to the subject device have been evaluated through successful performance testing, with no safety or effectiveness concerns identified. These differences do not impact on the overall performance, functionality, or intended use of the device.

## 6. NON-CLINICAL PERFORMANCE DATA

The subject devices 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 subject devices 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 ST98:2022 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 subject devices. The device is not provided sterile; therefore, shelf-life is not applicable.

iii. Biocompatibility

The biocompatibility characteristics of the subject devices are identical to those of the predicate device. There are no changes in the type of tissue contact, or the duration of contact compared to the predicate device. The biological risks associated with the subject devices have been determined to be acceptable.

iv. Software and Cybersecurity

Additional software verification and validation are not required, as no software changes have been made. Cybersecurity assessments are also not required because the subject devices have no network connection.

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

Performance bench testing related to mechanical, transport/environment, chemical durability, and compatibility with disinfectants and sterilizer/AER systems were conducted and met the acceptance criteria. The system performances of the subject devices demonstrated equivalence to the predicate devices.

vii. Optical Performance

Additional optical performance tests are not required, as no modifications or updates which affect optical performance have been made to the subject devices.

viii. Human Factors study

PENTAX Medical conducted a gap analysis between the pre-modification and post-modification versions of the Reprocessing Instruction for Use, in accordance with FDA's 2016 HFE guidance "*Applying Human Factors and Usability Engineering to Medical Devices*". As the result of the analysis, PENTAX Medical determined that no new critical tasks were introduced by the changes, and therefore, Human Factors study is not required.

**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 devices are as safe and effective as the predicate devices. There are no differences in the indications for use or intended use between the subject and predicate devices; therefore, they are considered substantially equivalent.

## 7. CONCLUSION

The subject devices do not pose any questions regarding safety or effectiveness. They are deemed to be substantially equivalent to the identified predicate devices: PENTAX Medical Video Upper GI Scopes (EG Family) (K131902) and PENTAX Medical Video Colonoscopes (EC Family) (K131855).