May 13, 2021

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

Re: K210485
Trade/Device Name: PENTAX Medical Video Upper GI Scopes (EG Family),
PENTAX Medical Video Colonoscopes (EC Family)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FDS, FDF
Dated: February 17, 2021
Received: February 19, 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, 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)*
K210485

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

Indications for Use *(Describe)*

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.

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.

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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PENTAX Medical Video Upper G.I. scopes (EG Family) and Colonoscopes (EC Family)- 5 rIFUs
Traditional 510(k) Submission

510(k) Summary

I. SUBMITTER

PENTAX of America, Inc.,
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3 Paragon Drive
Montvale, New Jersey 07645-1782
Phone: 201-571-2318 Ext 2318
Fax: 201-571-2340

Contact: William Goeller
Date Prepared: February 17, 2021

II. DEVICE

The purpose of this 510(k) is to obtain clearance for the simplified reprocessing instructions which are separated into (5) rIFU's to eliminate the need for reprocessing personnel to identify what configuration endoscope they are working with.

There are no other changes to the reprocessing instructions for use, nor are there any changes to the design, intended use, or indications for use of the EG Family and EC Family of endoscopes.

Table 5.1: Regulatory Classification of PENTAX Medical Video Upper GI Scopes.

Device Name	PENTAX Video Upper GI Scopes (EG Family)
510(k) Number	K131902
Common Name	Gastroscope And Accessories, Flexible/Rigid
Classification Name	Endoscope and accessories
Regulation No.	876.1500
Device Class	2
Product Code	FDS
Classification Panel	Gastroenterology/ Urology

Table 5.2: Regulatory Classification of PENTAX Medical Video Colonoscopes

Device Name	PENTAX Video Colonoscopes (EC Family)
510(k) Number	K131855
Common Name	Colonoscopes And Accessories
Classification Name	Endoscope and accessories
Regulation No.	876.1500

PENTAX Medical Video Upper G.I. scopes (EG Family) and Colonoscopes (EC Family)- 5 rIFUs
Traditional 510(k) Submission

Device Class	2
Product Code	FDF
Classification Panel	Gastroenterology/ Urology

III. PREDICATE DEVICES

The predicate devices for this submission are also the subject of this submission, the PENTAX Medical Video Upper G.I. scopes (EG Family) (K131902) and PENTAX Medical Video Colonoscopes (EC Family) (K131855). The predicate devices are identical to the devices subject to this 510(k); the only change relates to the reprocessing instructions that are now broken down into 5 separate manuals for each endoscope type.

IV. DEVICE DESCRIPTION

The subject devices are identical to the predicate devices. There are no changes to the design, specifications, or technological characteristics of the PENTAX Medical Video Upper GI Scopes and PENTAX Medical Video Colonoscopes as described in K131902 and K131855 respectively. The associated model numbers for the PENTAX Medical Video Upper GI Scopes are provided in Table 5.2.

Table 5.2: Model Numbers Associated with the PENTAX Medical Video Upper GI Scopes

PENTAX Video Upper G.I. scopes (EG Family)				
EG-2990i	EG-1690K	EG-2790K	EG-3490K	EG27-i10
EG-2790i	EG-2490K	EG-2990K	EG-3890TK	EG29-i10

The associated model numbers for the PENTAX Medical Video Colonoscopes are provided in Table 5.3.

Table 5.3: Model Numbers Associated with the PENTAX Medical Video Colonoscopes

PENTAX Video Colonoscopes (EC Family)				
EC-3890TLK	EC-3490Li	EC-3490TLi	EC-3890LK	EC34-i10L
EC-2990Li	EC-3890Li	EC-3490LK	EC-3890LZi	EC38-i10L

The PENTAX Medical Video Upper G.I. scopes (EG Family) and Colonoscopes (EC Family) are used with Video Processors. They are composed of three main components: 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, and Instrument Channel are located on the Distal End of the Insertion Portion. The Distal End also contains an Air/Water

Nozzle and Water Jet Nozzle. This Air/Water Feeding System is used to deliver the air and water to the Objective Lens.

The Control Body is held by the user's hand. The Control Body includes the Angulation Control lever used to operate the endoscope angulation; Suction Cylinder and Suction Nipple for suctioning fluid and air in the body cavity; Remote Button used to operate the function of video processor; and Instrument Channel Inlet used to insert endotherapy devices, such as biopsy forceps, into the body cavity.

The Magnification Control Lever is used to magnify the image on the video monitor, as necessary. As this magnification function is performed electrically, focus and depth of field are not changed.

The PVE Connector is connected to the Video Processor via an Electrical Contacts. The PVE Connector includes the Electrical Contacts and Light Guide Plug. The Light Guide Plug is connected to the Light Source inside the Video Processor. The Light Guide of the Distal End is used to illuminate the body cavity by light that is carried through the Light Carrying Bundle. The Light Carrying Bundle guides the light from Light Guide Plug that is connected to the Light Source. 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 Upper G.I. scopes and Colonoscopes are reusable semi-critical devices. Since they are packaged non-sterile, they must be high-level disinfected or sterilized before initial use. Prior to each subsequent procedure, they must be subjected to an appropriate cleaning and either high-level disinfection or sterilization processes.

V. INDICATIONS FOR USE

There are no changes to the Indications for Use for the subject devices. The sole purpose of this 510(k) is to simplify the reprocessing instructions by breaking two rIFU's into (5) to eliminate the need for reprocessing personnel to identify what configuration endoscope they are working with.

The PENTAX Medical Video Upper GI Scopes (EG Family) 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.

The PENTAX Medical Video Colonoscopes (EC Family) 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.

PENTAX Medical Video Upper G.I. scopes (EG Family) and Colonoscopes (EC Family)- 5 rIFUs
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VI. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE

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 design technological characteristics, 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 sole difference between the subject and predicate device is that the reprocessing instructions have been simplified by breaking down rIFUs into (5) separate groups. This modification does not impact the intended use and does not raise different questions of safety and effectiveness.

VII. PERFORMANCE DATA

The optimization of the reprocessing instructions for the PENTAX Medical Video Upper GI scopes and Colonoscopes do not affect the biocompatibility, electrical safety, electromagnetic compatibility, software verification and validation, or performance testing for the scopes.

VIII. HUMAN FACTORS

PENTAX Medical conducted a Summative Human Factors Study to validate the effectiveness and the risk management measures that are in place for the reprocessing of the EG29-i10 Video Gastroscope with a water jet channel. An ancillary study of the EC-3890TLK limited to its second therapeutic channel was carried out with the same group of stakeholders.

The combination of these 2 scopes provides adequate Human Factors evaluation of all design features of EG/EC families related to reprocessing.

As a result of testing, use errors, close calls and difficulties were observed to have occurred in some critical tasks. However, it is estimated that the risks identified, and the root causes assigned to those risks can be reduced and/or mitigated via additional modifications of the rIFU design and the further refinement of the training materials.

VIII. CONCLUSION

The subject devices are identical to the predicate devices. The subject devices have the same intended use and technological characteristics as the predicate devices. There are no changes to the design of the subject devices.

The data submitted support the separation of reprocessing instructions into 5 groups for the PENTAX Medical Video Upper G.I. scopes and Colonoscopes demonstrate that the scopes can be reprocessed in a safe and effective manner.

The data provided in this 510(k) Premarket Notification support the equivalence of the subject and predicate devices.