January 18, 2019

PENTAX of America, Inc.
James W. Monroe
Director, Regulatory Affairs
3 Paragon Drive
Montvale, NJ 07645-1782

Re: K181084
Trade/Device Name: PENTAX Video Colonoscopes (EC Family)
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDF
Dated: December 18, 2018
Received: December 19, 2018

Dear James W. Monroe:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel G. Walter Jr -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K181084

Device Name

PENTAX Medical Video Colonoscopes (EC Family)

Indications for Use *(Describe)*

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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PENTAX Medical Video Colonoscopes (EC Family) Optimized IFU
Traditional 510(k) Submission

510(k) Summary

I. SUBMITTER

PENTAX of America, Inc.,
HOYA Corporation PENTAX Division
3 Paragon Drive
Montvale, New Jersey 07645-1782
Phone: 201-571-2300 Ext 2129
Fax: 201-571-2340

Contact: James W. Monroe Date
Prepared: April 14, 2018

II. DEVICE

The purpose of this 510(k) is to obtain clearance for revised reprocessing instructions which include optimized manual pre-cleaning and cleaning instructions for the PENTAX Medical Video Colonoscopes (EC Family), its components, and its accessories. 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 EC Family of endoscopes.

Table 5.1: Regulatory Classification of PENTAX Medical Video Colonoscopes.

Device Name	PENTAX Video Colonoscopes (EC Family)
510(k) Number	K131855
Common Name	Colonoscope and Accessories, Flexible/Rigid
Classification Name	Endoscope and accessories
Regulation No.	876.1500
Device Class	2
Product Code	FDF
Classification Panel	Gastroenterology/ Urology

III. PREDICATE DEVICES

The predicate device for this submission is also the subject of this submission, the PENTAX Medical Video Colonoscopes (EC Family) (K131855). The predicate device is identical to the device subject to this 510(k); the only change relates to the manual pre-cleaning and cleaning portions of the reprocessing instructions to streamline the instructions and improve clarity. No changes are being made to the high-level disinfection instructions or any other portion of the instructions for use.

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IV. DEVICE DESCRIPTION

The subject device is identical to the predicate device. There are no changes to the design, specifications, or technological characteristics of the PENTAX Medical Video Colonoscopes as described in K131855. The associated model numbers for the PENTAX Medical Video Colonoscopes are provided in Table 5.2.

Table 5.2: 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 Colonoscopes (EC Family) are used with Video Processors. They are composed of three main components: an Insertion Portion, Control Body, and PVE Connector.

The Insertion Portion is inserted into the body cavity of the 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, a Suction Cylinder and Suction Nipple for suctioning fluid and air in the body cavity, Remote Buttons used to operate the function of video processor, and an Instrument Channel Inlet used to insert endotherapy devices, such as biopsy forceps, into the body cavity.

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 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.

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V. INDICATIONS FOR USE

There are no changes to the Indications for Use for the subject device. The sole purpose of this 510(k) is to modify the manual pre-cleaning and cleaning portions of the instructions to streamline them and improve clarity. No changes are being made to the high-level disinfection instructions.

This instrument is intended to be used with a PENTAX Video processor (including light source), documentation equipment, Monitor, Endotherapy Devices 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.

VI. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE

The subject device is identical to the predicate device. The subject device has the same fundamental technology and operating principles of the predicate device, including the same intended use and design technological characteristics, such as Insertion Portion, Control Body and fiberoptics illumination. There are no differences in specifications, including, but not limited to, 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 modified. 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 Colonoscopes do not affect the biocompatibility, electrical safety, electromagnetic compatibility, software verification and validation, or performance testing for the scopes.

Reprocessing validation data is provided to support the equivalence of the subject and predicate devices, including soil accumulation and cleaning efficiency studies.

VIII. CONCLUSION

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

The data submitted support the revised reprocessing instructions for the PENTAX Medical Video Colonoscopes and demonstrate that the endoscopes can be reprocessed in a safe and effective manner.

PENTAX Medical Video Colonoscopes (EC Family) Optimized IFU
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The data provided in this 510(k) Premarket Notification support the equivalence of the subject and predicate devices.