October 12, 2018

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

Re: K180292
Trade/Device Name: PENTAX Medical Video Upper GI Scope EG34-i10
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDS
Dated: September 14, 2018
Received: September 17, 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,

Jeffrey W. Cooper
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2018.10.12
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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)*
K180292

Device Name
PENTAX Medical Video Upper GI Scope EG34-i10

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 upper digestive tract including the esophagus, stomach, and duodenum.

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 Upper GI Scope EG34-i10
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: 800-431-5880 Ext 2129
Fax: 201-571-2340

Contact: James Monroe
Date Prepared: January 31, 2018

II. DEVICE

The purpose of this 510(k) is to obtain clearance of the PENTAX Medical Video Upper GI Scope EG34-i10.

Table 5.1: Regulatory Classification of PENTAX Medical Video Upper GI Scope EG34-i10.

Device Name	PENTAX Medical Video Upper GI Scope EG34-i10
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

III. PREDICATE DEVICES

The predicate device for this submission, PENTAX Video Upper GI Scopes EG29-i10 (K131902), is virtually identical to the PENTAX Medical Video Upper GI Scope EG34-i10. The subject and predicate devices differ slightly with regard to dimensional specifications and materials.

IV. DEVICE DESCRIPTION

The PENTAX Medical Video Upper GI Scope EG34-i10 is intended to provide optical visualization of (via a video monitor), and therapeutic access to, the upper gastrointestinal tract. The PENTAX Medical Video Upper GI Scope EG34-i10 is compatible with the PENTAX Medical EPK-i7010 Video Processor (K150618) and PENTAX Medical EPK-i5010 Video Processor (K143727).

The PENTAX Medical Video Upper GI Scope EG34-i10 is composed of three main components: an 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

Distal End of the Insertion Portion includes the Objective Lens, Light Guide, Instrument Channel, Air/Water Nozzle, and Water Jet Nozzle.

The Air/Water Feeding System is used to deliver the air and water to the Objective Lens from the Air/Water Nozzle. The Air/Water Feeding Valve is attached to the Air/Water Cylinder. When the hole at the top of Air/Water Feeding Valve is covered, the air is delivered. When the Air/Water Feeding Valve is pushed, the water is delivered. A Water Jet System is used to stream forward the sterile water from the Water Jet Nozzle.

The Control Body is held by the user's hand. The Control Body includes the Angulation Control Knob, Angulation Lock Knob/Lever, Air/Water Cylinder, Suction Cylinder, Remote Control Button, and Instrument Channel Inlet. The Bending Section is bent by the Angulation Control Knob to operate the endoscope angulation. The Angulation Lock Knob/Lever is used to adjust the rotation torque of the Angulation Control Knob. The Remote Button is used to operate the function of video processor and external device from the control body, as necessary.

The Inlet Seal is attached to the Instrument Channel Inlet. Endotherapy Device such as Biopsy Forceps may be inserted from the Instrument Channel Inlet into the body cavity through the instrument channel.

The PVE Connector is connected to the Video Processor via an Electrical Contacts. 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 inside the video processor. 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 is 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 GI Scope EG34-i10 is a reusable semi-critical device. Since it is packaged non-sterile, it must be high-level disinfected or sterilized before initial use. Prior to each subsequent procedure, it must be subjected to an appropriate cleaning and either high-level disinfection or sterilization processes.

V. INDICATIONS FOR USE

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.

VI. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE

The subject device is virtually 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 optical characteristics. The minor differences between the subject and predicate devices

exist with regard to dimensional specifications and materials. These modifications do not impact the intended use and do not raise different questions of safety and effectiveness.

VII. PERFORMANCE DATA

a. Reprocessing Validation

The PENTAX Medical PENTAX Medical Video Upper GI Scope EG34-i10 is 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.

The following testing has been performed for the PENTAX Medical Video Upper GI Scope EG34-i10:

- Soil Accumulation Study
- Cleaning Efficacy Study
- High Level Disinfection (HLD) Efficacy Study
- Rinsing Validation
- Sterilization Validation

All acceptance criteria were satisfied.

b. Biocompatibility

The biocompatibility evaluation of the patient contacting materials of the PENTAX Medical Video Upper GI Scope EG34-i10 was conducted in accordance with "Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process' (June 16, 2016)" with passing results.

c. Electrical Safety and Electromagnetic Compatibility (EMC)

The PENTAX Medical Video Upper GI Scope EG34-i10 complies with the following standards for electrical safety and EMC.

Electrical Safety

- IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012
- IEC 60601-2-18:2009
- ANSI/AAMI ES60601-1:2005 + A2:2010 + A1:2012

Electromagnetic Capability

- IEC 60601-1-2:2007/EN 60601-1-2:2007

d. Software Verification and Validation

The subject devices utilize the same software as the predicate device.

e. Performance Testing

Optical Testing

PENTAX Medical Video Upper GI Scope EG34-i10
Traditional 510(k) Submission

PENTAX Medical completed optical testing of the PENTAX Medical Video Upper GI Scope EG34-i10 compared to the predicate, PENTAX Medical Video Upper GI Scope EG29-i10. The scopes were evaluated for Light Distribution, Spectral Distribution, Total Luminous Flux, and Photobiological Safety. Testing was conducted using both the PENTAX Medical EPK-i5010 and EPK-i7010 Video Processors. The results of the testing indicate that the light distributions, intensity and wavelength, and total luminous flux of the PENTAX Medical Video Upper GI Scope EG34-i10 were comparable to the PENTAX Medical Video Upper GI Scope EG29-i10.

The photobiological safety of the lamps and lamp systems was evaluated in accordance with IEC 62471, Photobiological safety of lamps and lamp systems. Testing revealed that IEC 62471 evaluation values of all subject and predicate device combinations are risk group 2 or lower, and the safety of the subject device combinations are considered to be equivalent to the predicate device combinations.

Usability Testing

A comparison of the usability of the NTAX Medical Video Upper GI Scope EG34-i10 to PENTAX Medical i10 and k10 series of scopes was conducted. The i10 series of scopes include the predicate device, EG29-i10. Usability testing of various operating conditions was performed which demonstrated that there is no difference in all operations and their usability is equivalent.

VIII. CONCLUSION

The subject device is virtually identical to the predicate device with only minor changes to materials and dimensional specifications. The intended use of the subject and predicate devices are identical. Any differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness.

The data submitted support the performance and reprocessing for the PENTAX Medical Video Upper GI Scope EG34-i10 and demonstrate that the scope performs as intended and 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.