October 20, 2021

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

Re: K210177
Trade/Device Name: PENTAX Medical Video Upper GI Scope EG17-J10
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDS
Dated: September 15, 2021
Received: September 16, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210177

Device Name
PENTAX Medical Video Upper GI Scope EG17-J10

Indications for Use *(Describe)*
The PENTAX Medical Video Upper GI Scope EG17-J10 is intended to provide optical visualization of (via a video monitor), and therapeutic access to, the upper gastrointestinal tract. This anatomy includes the organs, tissues, and subsystems of esophagus, stomach and duodenum.
This endoscope is introduced via the mouth or nose when indications consistent with the need for the procedure are observed in adult and pediatric patient populations.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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
HOYA Corporation PENTAX Division
3 Paragon Drive
Montvale, New Jersey 07645-1782

Contact: William Goeller
Vice President, Quality and Regulatory Affairs
PENTAX Medical
3 Paragon Drive
Montvale, New Jersey 07645-1782
Telephone: (201)571-2300 ext. 2318
FAX: (201)391-4189
Email: william.goeller@pentaxmedical.com

Date Prepared: 10/19/2021

2 SUBJECT DEVICE

PENTAX Medical is seeking clearance of a new product of PENTAX Medical Video Upper GI scope EG17-J10 with the compatible PENTAX Medical Video Processors EPK-i5010, EPK-i7010 and EPK-3000. This 510(k) also captures some minor design changes that have occurred during the evolution of the product line. Although the changes are believed to be minor, the 510(k) is being submitted to account for technological advances in associated compatible devices and to ensure that FDA has the most current information concerning the PENTAX Medical Video Upper GI scope EG17-J10.

The regulatory classification of PENTAX Medical Video Upper GI Scope EG17-J10 is identified in Table 5.1.

Table 5.1: Regulatory Classification of PENTAX Medical Video Upper GI Scope EG17-J10

Device Names	PENTAX Medical Video Upper GI Scope EG17-J10
Common Name	Gastroscope and Accessories, Flexible/Rigid
Classification Name	Endoscope and accessories
Regulation No.	876.1500
Device Class	II
Product Code	FDS
Classification Panel	Gastroenterology/Urology

3 PREDICATE DEVICE

The predicate device for this submission is PENTAX Video Upper G.I. Scope EG-1690K which is included in PENTAX Video Upper G.I. Scopes (EG Family) (K131902).

The subject device has the same indications for use but there are some minor design changes from the predicate device. The main differences between the predicate and subject devices are summarized:

- Due to technological advances, the optical design of the subject device EG17-J10 has been modified. Specifically, its sensor module assembly is different with respect to the predicate device. The optical performance of the predicate and subject devices has been confirmed to be substantially equivalent through bench testing and animal imaging study results.
- Device firmware and CCD has been updated to reflect technological modernization with higher resolution CCD.

4 DEVICE DESCRIPTION

PENTAX Medical Video Upper GI Scope EG17-J10

The PENTAX Medical Video Upper GI Scope EG17-J10 is intended to be used with a PENTAX Video Processor, video monitor, endoscopic device and other ancillary equipment for optical visualization (via a video monitor) of, and/or therapeutic access to the Upper Gastrointestinal Tract. This anatomy includes the organs; tissues; and subsystems: Esophagus, Stomach and Duodenum.

The EG17-J10 is composed of the following main parts: 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 objective lens, light guide, instrument channel and air/water nozzle are located on the distal end of the insertion portion. 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 button, and instrument channel inlet. The air/water feeding valve is attached to the air/water cylinder, and the suction control valve is attached to the suction cylinder. The inlet seal is attached to the instrument channel inlet. The PVE connector is connected to the video processor via electrical contacts.

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 air/water feeding system is used to deliver the air and water to the objective lens from the air/water nozzle. 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. The suction control system is used to suction the fluid and air in body cavity from the instrument channel. When the suction control valve is pushed, the fluid and air are suctioned.

The remote button is used to operate the functions of the video processor and any external device from the control body, as necessary.

Endoscopic devices such as biopsy forceps are inserted from the instrument channel inlet into the body cavity through the instrument channel.

The light guide of the distal end is used to illuminate the body cavity by light which is carried through the light carrying bundle. The light carrying bundle guides the light from light guide plug which 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 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 Processors EPK-i5010, EPK-i7010 and EPK-3000 are compatible with PENTAX Medical Video Upper GI Scope EG17-J10.

The PENTAX Medical Video Upper GI Scope EG17-J10 is provided with the following accessories:

- Inlet Seal - prevents suctioned fluid from coming out of the Instrument Channel Inlet during the use of suction function. During reprocessing, it seals the instrument Channel Inlet in order to fill the chemical solution inside the channel.
- Bite Block - prevents patients from biting the endoscope insertion tube during an endoscopic examination.
- Suction Control Valve - intended to control suction.
- Air/Water Valve - intended to control air and water feeding.

Additional accessories for reprocessing are provided with the device. These include a Cleaning Adapter, Soaking Cap, Ventilation Cap, Endoscope Cleaning Brush Kits, and replacement O- Rings.

PENTAX Medical Scope Stand (General accessory)

The PENTAX Medical Scope Stand is consisted of the PENTAX Medical Scope Stand (SS-1) and the PENTAX Medical Single Use Scope Holder (SCH-G2). This scope stand allows physicians to transfer the weight of the endoscope during an endoscopic procedure, and is a general accessory that can be used with other PENTAX Medical Video GI Scopes.

This scope holder is designed to hold the endoscope control body at a swivel joint in a

desired angle during an endoscopic procedure. The scope holder is disposable and sterilized for single use.

5 INTENDED USE AND INDICATIONS FOR USE

The PENTAX Medical Video Upper GI Scope EG17-J10 is intended to provide optical visualization of (via a video monitor), and therapeutic access to, the upper gastrointestinal tract. This anatomy includes the organs, tissues, and subsystems of esophagus, stomach and duodenum.
This endoscope is introduced via the mouth or nose when indications consistent with the need for the procedure are observed in adult and pediatric patient populations.

6 COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE

The PENTAX Medical Video Upper GI Scope EG17-J10 is functionally equivalent to the predicate device, the PENTAX Video Upper G.I. Scope EG-1690K (K131902). The main difference between the subject and the predicate are minor technological changes.

The changes in the subject device have been evaluated through performance testing and raise no issue of safety and effectiveness of the device as these differences have no effect on the performance, function or general intended use of the device.

The components of the PENTAX Medical Video Upper GI Scope EG17-J10 has the same fundamental technology and operating principles as the predicate device. Both the PENTAX Medical Video Upper GI Scope EG17-J10 and the predicate device are intended for illuminating and viewing the inside of the human body. The components of the PENTAX Medical Video Upper GI Scope EG17-J10 consist of the same components as the predicate device, including:

- A video processor
- Video Upper GI Scopes to provide optical visualization of (via a video monitor), and therapeutic access to the Upper Gastrointestinal Tract.
- Accessories, including but not limited to a keyboard, foot switch, White Balance Adjuster, and Condenser Earth Cable

The subject device is identical or enhanced to the predicate device with regard to

- Scope working length

- Scope field of view
- Scope depth of field
- Scope tip angulation
- Software requirements

The patient contacting components of both the subject and predicate devices are biocompatible. Both subject and the predicate scopes are reprocessed by the user.

7 NON-CLINICAL PERFORMANCE DATA

The PENTAX Medical Video Upper GI Scope EG17-J10 has 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.

Operational and Reprocessing Instructions for Use are provided for the scope.

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 EG17-J10 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 ("FDA's 2015 Reprocessing Guidance"). 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 EG17-J10. The device is not provided sterile, therefore, shelf-life is not applicable.

The PENTAX Medical Single Use Scope Holder (SCH-G2) which is composition of the PENTAX Medical Scope Stand is provided as a single-use, sterile product. Ethylene Oxide sterilization was conducted and a shelf-life of 1 year after

sterilization was verified.

iii. *Biocompatibility*

Biocompatibility of the EG17-J10 scope on direct and indirect contact materials was confirmed by assessing the cytotoxicity, sensitization, and intracutaneous reactivity. 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 Guidances for Industry and Staff "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.*", "*Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*" and "*Postmarket Management of Cybersecurity in Medical Devices.*"

v. *Electrical Safety and EMC*

The acceptable level of electrical safety (ES) and electromagnetic compatibility (EMC) for the PENTAX Medical Video Upper GI Scope EG17-J10 were confirmed by the following standards:
IEC 60601-1-2:2014; IEC 60601-1:2005+CORR 1:2006+CORR 2:2007+A1:2012; and IEC 60601-2-18:2009.

vi. *System Performance*

The system performance of the subject device demonstrated the equivalence to the predicate device. Test results also demonstrated six years of the service life for the EG17-J10. The service life for the Scope Stand SS-1 was verified five years.

vii. *Optical Performance*

As a part of Design Verification and Validation, optical properties of imaging and illumination performances were measured for the PENTAX Medical Video Upper GI Scope EG17-J10 in conjunction with the EPK-i7010, EPK-i5010 and EPK-3000 Video Processors. All results show that the optical characteristics of the subject device is 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 PENTAX Medical Video Upper GI Scope EG17-J10 is as safe and effective as the predicate device. There are no differences in indications for use and intended use between the subject and predicate device and are therefore, substantially equivalent. The technological differences in terms of design features, performance characteristics and constituent materials are not substantive.

8 CONCLUSION

Accordingly, PENTAX Medical believes the PENTAX Medical Video Upper GI Scope EG17-J10 is substantially equivalent to the identified predicate, the PENTAX Video Upper G.I. Scope EG-1690K, cleared by FDA in 2014 (K131902).