July 23, 2020

PENTAX of America, Inc.
William Goeller
Vice President, Quality/Regulatory Affairs
3 Paragon Drive
Montvale, NJ 07645-1782

Re: K200090
Trade/Device Name: PENTAX Medical EG-J10U Endoscopic Ultrasound System
EG34-J10U Ultrasound Upper GI Video Scope (Convex Array Type), EG36-J10UR Ultrasound Upper GI Video Scope (Radial Array Type), EG38-J10UT Ultrasound Upper GI Video Scope (Convex Array Type)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: ODG, ITX
Dated: June 29, 2020
Received: July 2, 2020

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)*
K200090

Device Name
PENTAX Medical EG-J10U Endoscopic Ultrasound System
EG34-J10U Ultrasound Upper GI Video Scope (Convex Array Type), EG36-J10UR Ultrasound Upper GI Video Scope (Radial Array Type) , EG38-J10UT Ultrasound Upper GI Video Scope (Convex Array Type)

Indications for Use *(Describe)*
The PENTAX Medical EG-J10U Endoscopic Ultrasound System is intended to provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the Upper Gastrointestinal Tract including but not restricted to the organs, tissues, and subsystems: Esophagus, Stomach, Duodenum and underlying areas. The instrument is introduced per orally when indications consistent with the requirement for 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."

PENTAX Medical EG-J10U Endoscopic Ultrasound System
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 21 CFR 807.92. All data included in this document is accurate and complete to the best of PENTAX Medical's knowledge.

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: 1/14/2020

Common Name: Endoscopic Ultrasound / Ultrasound Gastroscope
Device/Trade Name: PENTAX Medical EG-J10U Endoscopic Ultrasound System-EG34-J 10U Ultrasound Upper GI Video Scope (Convex Array Type), EG36-J10UR Ultrasound Upper GI Video Scope(Radial Array Type), EG38-J10UT Ultrasound Upper GI Video Scope (Convex Array Type)

Regulation Number: 21 CFR Part 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Codes: ODG, ITX
Predicate Device: PENTAX Medical Endoscopic Ultrasound System (K182004) PENTAX Medical is seeking clearance of a new line of ultrasound upper GI video scopes EG-J10U with the Pentax Video Processors EPK-i5010 and EPK-i7010, for use with Hitachi's HI VISION Preirus and ARIETTA 70. PENTAX Video Processors EPK-i5010 (K122470) and EPK-i7010 (K150618) as well Hitachi HI VISION Preirus (K093466) and ARIETTA 70 (K134016) have been previously cleared.

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 Ultrasound Upper GI Video Scopes

The subject devices have virtually the same indications for use, viewing directions, and image size as the predicates. The subject devices use the same processors and peripherals as the predicate device.

The main differences between the subject devices and predicate devices are as follows:

- Introduction of a new line of ultrasound upper GI video scopes EG-J10U, which includes EG34-J10U, EG36-J10UR and EG38-J10UT as compatible Ultrasound Upper GI Video Scopes.
- A Reprocessing Instructions for Use (rIFU) that demonstrates a streamlined, easy-to-follow format that is the output of Human Factors Testing.

Device Description:

The EG34-J10U, EG36-J10UR and EG38-J10UT Ultrasound Upper GI Video Scopes, are endoscopes used to provide visualization of, and therapeutic access to, the upper gastrointestinal tract. They are used with cleared Pentax Video Processors (a software-controlled device) and cleared Hitachi Ultrasound Scanners (a software-controlled device). The endoscopes have a flexible insertion tube, a control body, PVE umbilical connector, and ultrasound scanner umbilical connector. The PVE umbilical connector will be attached to the Video Processor and has connections for illumination, video signals, air/ water/ and suction.

The ultrasound scanner umbilical connector will be attached to the ultrasound scanner unit. A sterile, single use disposable natural rubber latex balloon is fitted over the convex array ultrasound transducer prior to the procedure. During an ultrasound endoscopy procedure, the latex balloon is inflated with water. The water that is contained within the balloon creates a water field that covers the transducer. The water field enables more effectively transport of ultrasonic pulses from the ultrasound transducer to the target anatomical site and back to the ultrasound transducer.

The control body includes controls for up/ down/ left/ right angulation, air/ water delivery, and an accessory inlet port. The endoscope contains light carrying bundles to illuminate the body cavity, a charge couple device (CCD) to collect endoscopic image data, and a linear or radial array ultrasound transducer to collect ultrasonic image data. The instrument contains a working channel through which biopsy devices, or other devices, may be introduced.

The video processor contains a lamp that provides white light and is focused at the PVE connector light guide prong. The endoscope light carrying bundles present the light to the body cavity and the CCD collects endoscopic image data. Image data and other screen display information are formatted and presented to the video outputs of the video processor for display.

The ultrasound transducer delivers ultrasonic pulses, reflections of the pulses are received, and the signals are passed to the ultrasound scanner for processing and display. EG34-J10U, EG36-J10UR, and EG38-J10UT Ultrasound Upper GI Video Scopes are connected to the ultrasound scanner Arietta 70 via the scanning unit connector of the endoscope directly to the probe connector of the scanning unit. In order to connect to the Preirus scanning unit, junction box PUN-JBP1 is required to connect the scanning unit connector to the probe connector.

The instrument is immersible (with the use of supplied cleaning accessories) except for the ultrasound scanner connector (as described in the endoscope operator manual cleaning instructions)

Intended Use
The PENTAX Medical Ultrasound Upper GI Video Scopes (EG34-J10U, EG36-J10UR, and EG38-J10UT) are intended to provide optical and ultrasound visualization of (via a video monitor), and therapeutic access to the upper gastrointestinal tract including the organs; tissues; and subsystems: esophagus, stomach and duodenum.

Indications for use
The PENTAX Medical EG-J10U Endoscopic Ultrasound System is intended to provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the Upper Gastrointestinal Tract including but not restricted to the organs, tissues, and subsystems: Esophagus, Stomach, Duodenum and underlying areas. The instrument is introduced per orally when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

Summary of Technology Characteristics:
The PENTAX Medical EG-J10U Endoscopic Ultrasound System is functionally equivalent to its predicate device, the PENTAX Medical Endoscopic Ultrasound System cleared by FDA in 2018. The only difference between the two devices is that the predicate is used with the Legacy Ultrasound Video Gastroscopes, and the subject is used with the additional EG-J10U series of Ultrasound GI Video Scopes that includes EG34-J10U, EG36-J10UR and EG38-J10UT

The additional devices 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.

Non-Clinical Performance Data

The PENTAX Medical EG-J10U Endoscopic Ultrasound System has been successfully tested for its 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 scopes.

Human Factors

A human factors study to assess the ability of reprocessing staff to carry out the reprocessing instructions for use (rIFU) was conducted. The device was been found to be safe and effective for the intended patients, intended users, and in their use environments.

Reprocessing Validation

Simulated use testing, soil accumulation analysis, cleaning, and high-level disinfection validation studies of the EG34-J10U, EG36-J10UR and EG38-J10UT Upper GI Video Scopes and accessories were conducted and confirmed the effectiveness of reprocessing procedures.

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 EG-J10U series Ultrasound Upper GI Video Scopes. The devices are not provided sterile.

PENTAX Medical conducted Gamma Ray Sterilization for packaging and for PENTAX Medical Ultrasound Balloons made of natural rubber latex. A shelf-life of 2 years after sterilization was verified.

The labeling for the PENTAX Medical Ultrasound Balloons and their packaging prominently bears the 21 CFR 801.437 warning in bold: **Caution: This product contains natural rubber latex which may cause allergic reactions.** Also, the Operating Instructions for Use of the EG-J10U series of Ultrasound Upper GI Video Scopes prominently bears the warning in bold: **Caution: The balloon contains natural rubber latex which may cause allergic reactions.**

Software
Software verification and validation tests were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software is classified as CLASS A under the Software Safety Classification per IEC 62304:2006, Medical device software- Software life cycle processes. The software level of concern is "Moderate" based on FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Cybersecurity risks have been assessed and mitigated according to the FDA Guidances for Industry and Staff "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" issued October 2, 2014 and "Postmarket Management of Cybersecurity in Medical Devices." issued December 28,2016.

EMC and Electrical Safety
The acceptable level of electromagnetic compatibility (EMC) and electrical safety (ES) for the PENTAX Medical Endoscopic EG-J10U Ultrasound System were confirmed by the following standards:
IEC 60601-1-2:2007; IEC 60601-1:2005+CORR 1:2006+CORR 2:2007+A1:2012; IEC 60601-2-18:2009; and IEC 60601-2-37:2007.

Optical Testing
As a part of Design Verification and Validation, optical properties including signal to noise ratio, spatial resolution (MTF), distortion, light distribution, color (IEEE), spectral distribution and photobiological safety were measured for the EG34-J10U, EG36-J10UR and EG38-J10UT in conjunction with the EPK‐i5010 and EPK-i7010 video processors. All results show that there are no differences between the subject device, and 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, we conclude that the subject device PENTAX Medical EG-J10U Endoscopic Ultrasound System 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.

Conclusion:

Accordingly, PENTAX Medical believes the PENTAX Medical EG-J10U Endoscopic Ultrasound System is substantially equivalent to the identified predicate, the PENTAX Medical Endoscopic Ultrasound System, cleared by FDA in 2018.