DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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April 13, 2017

Pentax of America, Inc.
Krishna Govindarajan
Senior Manager, Regulatory Affairs
3 Paragon Drive
Montvale, NJ 07645-1782

Re: K162447
Trade/Device Name: PENTAX Medical Endoscopic Ultrasound System - EG-3270UK Upper G.I. Video Scope (Convex Array Type) with EPK-i5010 Video Processor and HI VISION Preirus Ultrasound Scanner
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Codes: ODG, ITX
Dated: February 28, 2017
Received: March 1, 2017

Dear Krishna Govindarajan:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

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)*
K162447

Device Name
PENTAX Medical Endoscopic Ultrasound System – EG-3270UK Upper G.I. Video Scope (Convex Array Type) with EPK-i5010 Video Processor and HI VISION Preirus Ultrasound Scanner

Indications for Use *(Describe)*
The PENTAX Medical Endoscopic Ultrasound System is intended to provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the Upper Gastrointestinal Track including but not restricted to the organs, tissues, and subsystems: Esophagus, Stomach, Duodenum, Small Bowel, 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.

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PENTAX MEDICAL

510(k) Summary

The following summary is provided in accordance with 21 CFR 807.92:

I. SUBMITTER

PENTAX of America, Inc.,
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3 Paragon Drive
Montvale, New Jersey 07645-1782

Phone: 201-251-2300 x 2125
Fax: 201-799-4117

Contact Person: Krishna Govindarajan
Date Prepared: August 31, 2016

II. DEVICE / SYSTEM

Name of System: PENTAX Medical Endoscopic Ultrasound System
EG-3270UK Upper G.I. Video Scope (Convex Array Type) with EPK-i5010 Video Processor (K122470) and HI VISION Preirus Ultrasound Scanner (K093466)

Common/Usual Name:	Endoscopic Ultrasound / Ultrasound Gastroscope
Regulation Number:	21 CFR Part 876.1500
Regulation Name:	Endoscope and accessories Diagnostic Ultrasound Transducer
Regulatory Class:	Class II
Product Code:	ODG and ITX

III. PREDICATE DEVICE

Predicate Device: PENTAX EG-3870UTK Ultrasound Video Gastroscope + HI VISION Preirus (K130247; dated March 20, 2013)

Regulation Number:	21 CFR Part 876.1500
Regulation Name:	Endoscope and accessories Diagnostic Ultrasound Transducer
Regulatory Class:	Class II
Product Code:	ODG and ITX

This reference device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The EG-3270UK, Ultrasound Upper GI Video Scope, is an endoscope used to provide visualization of, and therapeutic access to, the upper gastrointestinal tract. It is used with cleared Pentax Video processors (a software controlled device) and cleared Hitachi Ultrasound Scanner (a software controlled device)

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

V. INDICATIONS FOR USE

The PENTAX Medical Endoscopic Ultrasound System is intended to provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the Upper Gastrointestinal Track including but not restricted to the organs, tissues, and subsystems: Esophagus, Stomach, Duodenum, Small Bowel, 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The PENTAX Medical Endoscopic Ultrasound System - EG-3270UK Upper G.I. Video Scope (Convex Array Type) with EPK-i5010 Video Processor and HI VISION Preirus Ultrasound Scanner has the same fundamental technology and operating principles in comparison to those of the predicate device, including same intended use, design technological characteristics, such as Insertion Portion, Control Body and fiber-optics illumination. The minor differences in the Depth of Field, Distal end width, Insertion Tube width, instrument channel width, and Total Length between two devices do not impact the intended use, and do not raise different questions of safety and effectiveness and that the device is as safe and effective as a legally marketed device.

VII. PERFORMANCE DATA

The following performance data are provided in support of the substantial equivalence determination.

Biocompatibility Testing

Biocompatibility of direct and indirect contact materials were confirmed by testing the Cytotoxicity, Sensitization and Intracutaneous Reactivity of the materials of the of the EG-3270UK Upper G.I. Video Scope with limited (less than 24 hours) contact with mucosal membrane in accordance with the ISO 10993-1, 5, and 10 Biological Evaluation of Medical Devices.

Reprocessing Validation, Sterilization and Shelf Life

Reprocessing Validation

Simulated use testing, soil accumulation analysis, cleaning, and high level disinfection validation studies of the EG-3270UK Upper G.I. Video Scope and its accessories were conducted and confirmed the effectiveness of reprocessing procedures.

Sterilization and Shelf Life

PENTAX Medical validated the EG-3270UK Upper G.I. Video Scope with Ethylene Oxide Gas Sterilization method and confirmed the effectiveness of sterilization method. The device is not provided sterile, therefore, shelf-life is not applicable.

Electrical safety and electromagnetic compatibility (ES & EMC)

The acceptable level of Electromagnetic Compatibility (EMC) and Electrical Safety (ES) for the PENTAX Medical Endoscopic Ultrasound System has been confirmed by testing the EG-3270UK Upper G.I. Video Scope (Convex Array Type) with EPK-i5010 Video Processor and HI VISION Preirus Ultrasound Scanner in accordance with the following standards:

1. IEC 60601-1:1988+A1:1991+A2:1995 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-1:2000 Medical electrical equipment- Part 1-1: General requirements for safety- Collateral standard: Safety requirements for medical electrical systems

3. IEC 60601-1-2:2001+A1:2004 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
4. IEC 60601-1-4:2000 Ed. 1.1 Medical electrical equipment- Part 1-4: General requirements for safety- Collateral Standard: Programmable electrical medical systems
5. IEC 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
6. IEC 60601-2-18:1996+A1:2000 Medical electrical equipment- Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

Software Verification and Validation Testing

Software verification and validation testing 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 B under the Software Safety Classification per IEC 62304:2006, Medical device software - Software life cycle processes, and the software level of concern is "Moderate" based on the FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Acoustic output measurement

Acoustic output data of the PENTAX Medical Endoscopic Ultrasound System (EG-3270UK Upper G.I. Video Scope (Transducer) with EPK-i5010 Video Processor and HI VISION Preirus Ultrasound Scanner) were measured in accordance with the FDA's Guidance for Industry and FDA Staff, "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers".

VIII. CONCLUSIONS

After analyzing the intended use, indications for use, technological characteristics (including fundamental operating principle, energy source, scientific technology, functional characteristics, design features, and performance characteristics), labeling, and sterilization method, we conclude that the subject device, the PENTAX Medical Endoscopic Ultrasound System (EG-3270UK Upper G.I. Video Scope (Convex Array Type) with EPK-i5010 Video Processor and HI VISION Preirus Ultrasound Scanner), is substantially equivalent to the predicate, PENTAX EG-3870UTK Ultrasound Video Gastroscope + HI VISION Preirus (K130247; dated March 20, 2013). The minor differences in the Depth of Field, Distal end width, Insertion Tube width, instrument channel width, and Total Length between the two devices does not change the intended use, and/or raise different questions of safety and effectiveness.