May 23, 2019

PENTAX of America, Inc.
William Goeller
Vice President, Quality Assurance and Regulatory Affairs
3 Paragon Drive
Montvale, New Jersey 07645-1782

Re: K183654
Trade/Device Name: PENTAX Medical EB-1970UK Ultrasound Video Bronchoscope + Hitachi NOBLUS and HI VISION Preirus
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: April 24, 2019
Received: April 26, 2019

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/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,

for Michael Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental 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)*

K183654

Device Name

PENTAX Medical EB-1970UK Ultrasound Video Bronchoscope + Hitachi NOBLUS and HI VISION Preirus

Indications for Use *(Describe)*

The EB-1970UK, Ultrasound Video Bronchoscope, is intended to provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the Pulmonary Tract including but not restricted to organs, tissues, and subsystem: Nasal Passage, Pharynx, Larynx, Trachea, Bronchial Tree (including access beyond the stem), 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.

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PENTAX Medical EB-1970UK Ultrasound Video Bronchoscope + Hitachi NOBLUS and HI VISION Preirus
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.

Applicant: PENTAX Medical
HOYA Corporation PENTAX Division
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Date Prepared: December 21, 2018

Common Name: Endoscopic Ultrasound / Ultrasound Bronchoscope
Name of the System: PENTAX Medical EB-1970UK Ultrasound Video Bronchoscope + Hitachi NOBLUS and HI VISION Preirus
EB-1970UK with EPK-i5010 Video Processor (K131946), EPK-i7010 Video Processor (K173679) plus HI VISION Preirus Ultrasound Scanner (K093466) and NOBLUS Ultrasound Diagnostic System Ultrasound Scanner (K160559)
Regulation Number:
21 CFR Part 874.4680
Regulation Names:
Bronchoscopes (Flexible or rigid) and accessories
Diagnostic Ultrasound Transducer
Regulatory Class: Class II
Product Code: EOQ, ITX
Predicate Device: PENTAX Ultrasound Video Bronchoscope EB-1970UK + HI VISION Preirus(K131946)

The proposed PENTAX modification is to bundle the Ultrasound Video Bronchoscope EB-1970UK + Hitachi HI VISION Preirus Ultrasound Scanner and Pentax Video Processor EPK-i5010, for use with PENTAX Medical Video Processor EPK-i7010 and Hitachi's NOBLUS Ultrasound Diagnostic System Ultrasound Scanner. All the devices have been previously cleared.

This 510(k) 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 Video Bronchoscope, EB-1970UK, which in itself, has not changed from a design standpoint.

The subject device has the same indications for use, composition of patient contact materials, viewing direction, image size, and reprocessing/sterilization method as the predicate. The subject device uses the same processors and peripherals as the predicate device with two additions.

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

- Addition of the EPK-i7010 as a compatible Video Processor
- Addition of the Hitachi NOBLUS Ultrasound Diagnostic System as a compatible Ultrasound Scanner

Device Description:
The EB-1970UK, Ultrasound Video Bronchoscope, must be used with a Pentax Video Processor (a software-controlled device) and must be used with an 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 connector will be attached to the Video Processor and has connections for illumination and video signals. The ultrasound umbilical connector will be attached to the ultrasound scanner unit. The control body includes controls for up/down angulation, suction control, video processor remote control buttons, and ports for manual balloon insufflation/ evacuation and accessory inlet.

A sterile, single use disposable natural rubber latex balloon is fitted over the convex array ultrasound transducer prior to the procedure. It is designed to be inflated with a specific volume of water during the procedure so that the effective transport of ultrasonic pulses from the ultrasound transducer to the target anatomical site and back to the ultrasound transducer can take place. The endoscope contains light carrying bundles to illuminate the body cavity, a charge couple device (CCD) to collect endoscopic image data, and a convex 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 focused at the endoscope 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 immersible (with the use of supplied cleaning accessories).

Intended Use / Indications for use
The EB-1970UK Ultrasound Video Bronchoscope is intended to provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the Pulmonary Tract including but not restricted to organs, tissues, and subsystem: Nasal Passage, Pharynx, Larynx, Trachea, Bronchial Tree (including access beyond the stem), 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 Ultrasound Video Bronchoscope EB-1970UK + Hitachi NOBLUS and HI VISION PREIRUS is functionally equivalent to its predicate device, the PENTAX Ultrasound Video Bronchoscope EB-1970UK + HI VISION Preirus cleared by FDA in 2014. The only difference between the two devices is that the predicate can be used with the EPK-i5010 video processor and HI VISION Preirus Ultrasound scanner, whereas the subject device is now additionally compatible with the EPK-i7010 video processor and NOBLUS Ultrasound scanner.

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 Ultrasound Video Bronchoscope EB-1970UK + Hitachi NOBLUS and HI VISION Preirus Ultrasound Scanners 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.

Software

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 A 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."

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 EB-1970UK Ultrasound Video Bronchoscope + Hitachi NOBLUS and HI VISION Preirus were confirmed by the following standards: IEC 60601-1-2:2007; IEC 60601- 1:2005+CORR. 1:2006+CORR. 2:2007+A 1:2012; IEC 60601-2-18:2009 and IEC 60601-2-37:2007; IEC 60601-1:1988+A1+:1991+A2:1995 +CORR. 1:1995; IEC 60601-2-18:1996+A1:2000; IEC 60601-2-37:2001+A1:2004+A2:2005.

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 EB-1970UK Ultrasound Video Bronchoscope + Hitachi NOBLUS and HI VISION PREIRUS Ultrasound Scanner 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. The technological differences in terms of design features, performance characteristics and constituent materials are not substantive.

Conclusion:

Accordingly, PENTAX Medical believes the PENTAX Medical EB-1970UK Ultrasound Video Bronchoscope + Hitachi NOBLUS and HI VISION Preirus Ultrasound Scanners is substantially equivalent to the identified predicate, the PENTAX Ultrasound Video Bronchoscope EB-1970UK + HI VISION Preirus, cleared by FDA in 2014.