PENTAX
MEDICAL

K131946

APR 25 2014

510(k) Summary

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

Date: 25 Jun 2013

Submitter:	PENTAX Medical Company, HOYA Corporation PENTAX Division 3 Paragon Drive Montvale, New Jersey 07645-1782
Contact:	Krishna Govindarajan Regulatory Manager PENTAX Medical Company, 3 Paragon Drive Montvale, New Jersey 07645-1782 Phone: 800-431-5880 x 2125, 201-251-2300 x 2125 Fax: 201-799-4117 Email: Krishna.govindarajan@pentaxmedical.com
Trade/Device Name:	PENTAX Ultrasound Video Bronchoscope EB-1970UK + HI VISION Preirus
Common/Usual Name:	Endoscopic Ultrasound / Ultrasound Bronchoscope
Regulation Number: Regulation Name: Regulatory Class: Product Code:	21 CFR Part 874.4680 Bronchoscopes (Flexible or rigid) and accessories Diagnostic Ultrasound Transducer Class II EOQ and ITX
Predicate Device:	PENTAX EB-1970UK Ultrasound Video Bronchoscope + EUB 5500 (K081518; dated Sep 5 2008)
Regulation Number: Regulation Name: Regulatory Class: Product Code:	21 CFR Part 874.4680 Bronchoscopes (Flexible or rigid) and accessories Diagnostic Ultrasound Transducer Class II EOQ and ITX

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 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:

The EB-1970UK, Ultrasound Video Bronchoscope, is intended to provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the Pulmonary Track 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 Ultrasound Video Bronchoscope EB-1970UK 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.

Safety and Performance Data (Non-clinical tests)

Design Verification and Validation testing has been performed in accordance with Design control per 21 CFR Part 820.30. The performance of the PENTAX Ultrasound Video Bronchoscope EB-1970UK has been evaluated using the appropriate methodology as specified in the following FDA recognized consensus standards in conjunction with our in-house test protocols and use of external testing laboratories:

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. ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
5. ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
6. ISO 10993-10:2010 Biological evaluation of medical devices - Part 10:Tests for irritation and skin sensitization
7. 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
8. ISO 8600-1:2005 Optics and photonics - Medical endoscopes and endotherapy devices - Part 1: General requirements
9. ISO 8600-3:1997+A1:2003 Optics and optical instruments –Medical endoscopes and endoscopic accessories - Part 3: Determination of field of view and direction of view of endoscopes with optics
10. ISO 8600-4:1997 Optics and optical instruments -Medical endoscopes and certain accessories - Part 4: Determination of maximum width of insertion portion
11. AAMITIR12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers
12. AAMITIR30:2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
13. ANSI/AAMI TIR79:2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
14. IS013485:2003 Medical devices - Quality management systems - Requirements for regulatory purposes
15. ISO 14971:2007 (corrected version): Medical devices -Application of risk management to medical devices
16. IEC 60601-1-4:2000 Ed. 1.1 Medical electrical equipment- Part 1-4: General requirements for safety- Collateral Standard: Programmable electricalmedical systems
17. IEC 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

18. IEC 62366:2007 Medical devices -Application of usability engineering to medical devices
19. IEC 62304:2006 Medical device software- Software life cycle processes
20. IEC 604171SO 7000-DB-12M:2004 Graphical symbols for use on equipment- 12-month subscription to online database comprising all graphical symbols published in IEC 60417 and ISO 7000
21. ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements'
22. IEC 60878:2003 Graphical symbols for electrical equipment in medical practice

The PENTAX Ultrasound Video Bronchoscope EB-1970UK test results satisfy the acceptance criteria specified by the above applicable standards.

Biocompatibility Test

Biocompatibility of direct and indirect contact materials were confirmed by testing the Cytotoxicity, Sensitization and Intracutaneous Reactivity for the surface device, mucosal membrane contact less than 24 hours duration device category in accordance with the ISO 10993-1, 5, and 10 Biological evaluation of medical devices standard and the FDA's guidance the Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'.

Reprocessing Validation

Simulated use conditioned test samples were used in the Cleaning validation and High Level Disinfection validation studies for validating the effectiveness of the reusable Bronchoscope Reprocessing procedures/methodology in accordance with the FDA's Draft Guidance for Industry and FDA Staff Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling distributed in May 2, 2011, AAMI TIR 12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers, AAMI TIR 30:2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices, and AAMI TIR79:2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities. All the study results satisfy the acceptance criteria specified by the above applicable standards.

In addition, the Reprocessing Instructions (Manual) were validated based on the FDA's Draft Guidance for Industry and FDA Staff Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling distributed in May 2, 2011. The validation confirmed that the PENTAX Ultrasound Video Bronchoscope EB-1970UK, Reprocessing Instructions are complete, understandable, and can reasonably be executed by the user.

EMC and Electrical Safety

The acceptable level of Electromagnetic compatibility (EMC) and Electrical Safety (ES) for the PENTAX Ultrasound Video Bronchoscope EB-1970UK was confirmed by testing in accordance with the IEC 60601-1; IEC 60601-1-2; IEC 60601-1-4; IEC 60601-1-6; Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, Safety

requirements for medical electrical systems, Electromagnetic compatibility - Requirements and tests; and 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.

Substantial Equivalence discussion:

The PENTAX Ultrasound Video Bronchoscope EB-1970UK has the same intended use, fundamental technology and operating principles including design technological characteristics, such as Insertion Portion, Control Body and fiber-optics illumination in comparison to those of the predicate device. The minor dimensional 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.

Conclusion:

The PENTAX Medical Company believes that the PENTAX Ultrasound Video Bronchoscope EB-1970UK as indicated in this 510(k) premarket notification submission is to be as safe, as effective and substantially equivalent in performance to the above identified cleared predicate device/system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 25, 2014

PENTAX Medical Company
% Mr. Krishna Govindarajan
Regulatory Manager
3 Paragon Drive
Montvale, NJ 07645-1782

Re: K131946
Trade/Device Name: PENTAX Ultrasound Video Bronchoscope EB-1970UK+HI VISION Preirus
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ, ITX
Dated: April 14, 2014
Received: April 15, 2014

Dear Mr. 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" (21CFR 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 yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: PENTAX Ultrasound Video Bronchoscope EB-1970UK + HI VISION Preirus

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 Track 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.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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