September 6, 2019

PENTAX of America, Inc.
% Beryl Jeanne
Associate Regulatory Specialist
NAMSA Inc.
400 Highway 169, Suite 500
Minneapolis, Minnesota 55426

Re: K183516
Trade/Device Name: PENTAX Medical Ultrasound Video Bronchoscope EB19-J10U
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ, ITX
Dated: August 1, 2019
Received: August 5, 2019

Dear Beryl Jeanne:

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,

for Srinivas Nandkumar, Ph.D.
Assistant 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)*
K183516

Device Name
PENTAX Medical Ultrasound Video Bronchoscope EB19-J10U

Indications for Use *(Describe)*
The PENTAX Medical Ultrasound Video Bronchoscope EB19-J10U 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.

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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"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."

System: ARIETTA 70
Probe: EB19-J10U

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows.

Clinical Application		Mode of Operation					
General (TrackI only)	Specific (TrackI & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler
Ophthalmic	Ophthalmic						
Fetal Imaging & Other	Fetal						
	Abdominal						
	Intra-operative (Spec.)						
	Intra-operative (Neuro.)						
	Laparoscopic						
	Pediatric						
	Small Organ (Spec.)						
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esoph. (non-Card.)						
	Musculo-skel. (Convent.)						
	Musculo-skel. (Superfic.)						
	Intra-luminal						
	Endoscopy	P	P	P		P	P
Cardiac	Cardiac Adult						
	Cardiac Pediatric						
	Trans-esophageal (card.)						
	Other (Spec.)						
Peripheral Vessel	Peripheral vessel						
	Other (Spec.)						

N=new indication; P=previously cleared by FDA, K131946
E=added under Appendix E

System: Noblus
Probe: EB19-J10U

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows.

Clinical Application		Mode of Operation					
General (TrackI only)	Specific (TrackI & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler
Ophthalmic	Ophthalmic						
Fetal Imaging & Other	Fetal						
	Abdominal						
	Intra-operative (Spec.)						
	Intra-operative (Neuro.)						
	Laparoscopic						
	Pediatric						
	Small Organ (Spec.)						
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esoph. (non-Card.)						
	Musculo-skel. (Convent.)						
	Musculo-skel. (Superfic.)						
	Intra-luminal						
	Endoscopy	P	P	P		P	P
Cardiac	Cardiac Adult						
	Cardiac Pediatric						
	Trans-esophageal (card.)						
	Other (Spec.)						
Peripheral Vessel	Peripheral vessel						
	Other (Spec.)						

N=new indication: P=previously cleared by FDA, K160559
E=added under Appendix E

Indications for Use
510(k) Number: K183516
Device Name: PENTAX Medical Ultrasound Video Bronchoscope EB19-J10U

System: HI VISION Preirus
Probe: EB19-J10U

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows.

Clinical Application		Mode of Operation					
General (TrackI only)	Specific (TrackI & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler
Ophthalmic	Ophthalmic						
Fetal Imaging & Other	Fetal						
	Abdominal						
	Intra-operative (Spec.)						
	Intra-operative (Neuro.)						
	Laparoscopic						
	Pediatric						
	Small Organ (Spec.)						
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esoph. (non-Card.)						
	Musculo-skel. (Convent.)						
	Musculo-skel. (Superfic.)						
	Intra-luminal						
	Endoscopy	P	P	P		P	P
Cardiac	Cardiac Adult						
	Cardiac Pediatric						
	Trans-esophageal (card.)						
	Other (Spec.)						
Peripheral Vessel	Peripheral vessel						
	Other (Spec.)						

N=new indication: P=previously cleared by FDA, K162447
E=added under Appendix E

510(k) Summary

510(k) Number	K183516
Submitter	PENTAX of America, Inc.
Primary Contact	William Goeller Vice President, Quality Assurance and Regulatory Affairs PENTAX of America, Inc. 3 Paragon Drive Montvale, New Jersey 07645-1782
Preparation Date	June 21, 2019
Trade Name	PENTAX Medical Ultrasound Video Bronchoscope EB19-J10U
Classification Names	Bronchoscope (flexible or rigid) and accessories; Diagnostic ultrasonic transducer
Device Classification	Class II
Regulations	21 CFR 874.4680; 21 CFR 892.1570
Product Codes	EOQ, ITX
Predicate Device	PENTAX Ultrasound Video Bronchoscope EB-1970UK + HI VISION PREIRUS (K131946, decision date April 25, 2014)
Reference Devices	PENTAX Medical EPK-3000 Video Imaging System (K172156) PENTAX Medical EPK-i5010 Video Processor with EB Family of Scopes (K143727) PENTAX Medical EPK-i7010 Video Processor with EB Family of Scopes (K173679) Hitachi Arietta70 Diagnostic Ultrasound System (K134016) Hitachi Noblus™ Diagnostic Ultrasound Scanner (K142368) Hitachi HI VISION Preirus Diagnostic Ultrasound Scanner (K093466)

Device Description	The PENTAX Medical Ultrasound Video Bronchoscope EB19-J10U connects with a video processor and an ultrasound scanner, both of which are software controlled devices. The endoscope has a flexible insertion tube, a control body, PVE connector, and scanning unit connector. The PVE connector attaches to the video processor and has connections for illumination and video signals. The ultrasound umbilical connector attaches to the ultrasound scanner unit. The control body includes remote buttons for functions assigned from the video processor. It also includes controls for up/down angulation or neutral position, suction control, and ports for manual balloon insufflation/evacuation and accessory inlet. The endoscope contains light carrying bundles to illuminate the body cavity, a change couple device 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). EB19-J10U is connected to the ultrasound scanners Arietta 70 and Noblus 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).

Intended Use / Indications for Use	The PENTAX Medical Ultrasound Video Bronchoscope EB19-J10U 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.

System: ARIETTA 70
Probe: EB19-J10U

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows.

Clinical Application		Mode of Operation					
General (TrackI only)	Specific (TrackI & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler
Ophthalmic	Ophthalmic						
Fetal Imaging & Other	Fetal						
	Abdominal						
	Intra-operative (Spec.)						
	Intra-operative (Neuro.)						
	Laparoscopic						
	Pediatric						
	Small Organ (Spec.)						
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esoph. (non-Card.)						
	Musculo-skel. (Convent.)						
	Musculo-skel. (Superfic.)						
	Intra-luminal						
	Endoscopy	P	P	P		P	P
Cardiac	Cardiac Adult						
	Cardiac Pediatric						
	Trans-esophageal (card.)						
	Other (Spec.)						
Peripheral Vessel	Peripheral vessel						
	Other (Spec.)						

N=new indication: P=previously cleared by FDA, K131946
E=added under Appendix E

System: Noblus
Probe: EB19-J10U

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows.

Clinical Application		Mode of Operation					
General (TrackI only)	Specific (TrackI & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler
Ophthalmic	Ophthalmic						
Fetal Imaging & Other	Fetal						
	Abdominal						
	Intra-operative (Spec.)						
	Intra-operative (Neuro.)						
	Laparoscopic						
	Pediatric						
	Small Organ (Spec.)						
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esoph. (non-Card.)						
	Musculo-skel. (Convent.)						
	Musculo-skel. (Superfic.)						
	Intra-luminal						
	Endoscopy	P	P	P		P	P
Cardiac	Cardiac Adult						
	Cardiac Pediatric						
	Trans-esophageal (card.)						
	Other (Spec.)						
Peripheral Vessel	Peripheral vessel						
	Other (Spec.)						

N=new indication: P=previously cleared by FDA, K160559
E=added under Appendix E

System: HI VISION Preirus
Probe: EB19-J10U

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows.

Clinical Application		Mode of Operation					
General (TrackI only)	Specific (TrackI & III)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler
Ophthalmic	Ophthalmic						
Fetal Imaging & Other	Fetal						
	Abdominal						
	Intra-operative (Spec.)						
	Intra-operative (Neuro.)						
	Laparoscopic						
	Pediatric						
	Small Organ (Spec.)						
	Neonatal Cephalic						
	Adult Cephalic						
	Trans-rectal						
	Trans-vaginal						
	Trans-urethral						
	Trans-esoph. (non-Card.)						
	Musculo-skel. (Convent.)						
	Musculo-skel. (Superfic.)						
	Intra-luminal						
	Endoscopy	P	P	P		P	P
Cardiac	Cardiac Adult						
	Cardiac Pediatric						
	Trans-esophageal (card.)						
	Other (Spec.)						
Peripheral Vessel	Peripheral vessel						
	Other (Spec.)						

N=new indication: P=previously cleared by FDA, K162447
E=added under Appendix E

Technological Characteristics	The subject and predicate devices have the following identical technological characteristics: image supply, angulation control function, angulation lock function, elevator control function, instrument channel inlet, air/water feeding function, illumination, direction of view, field of view, depth of field, tip angulation, insertion tube width, insertion tube working length, minimum visible distance of biopsy forceps, type of CCD, both use software, scan direction, scan system, and scan angle. The subject and predicate devices have the following different but equivalent technological characteristics: suction control functions, distal end width, minimum instrument channel width, and acoustic frequency. A summary of the differences between the equivalent technological characteristics of the subject and predicate devices are as follows: Suction control function: The subject device accessory suction control valve is single-use. The predicate device accessory suction control valve is reusable. Distal end width: The predicate device distal end width is 0.1mm smaller than the predicate device. Minimum instrument channel width: The predicate device minimum instrument channel width is 0.2mm larger than the predicate device. Acoustic frequency: The predicate device acoustic frequency is 3MHz greater than the predicate device. These differences do not raise new questions of safety or effectiveness.

Testing Summary	Sterilization (Accessories Provided Sterile) • Sterilization • Packaging • Shelf Life Reprocessing • Soil accumulation • Cleaning validation • Rinsing validation study after cleaning process • HLD validation • Rinsing validation study after HLD process • Ethylene oxide sterilization for 100% EO Biocompatibility • Cytotoxicity • Sensitization • Irritation Software EMC + Electrical Safety Performance Testing - Bench • System compatibility • Optical characteristics
Sterilization	The subject and predicate devices are not provided sterile. The subject and predicate device accessories provided sterile have validated sterilization processes.
Packaging	The subject and predicate device accessories provided sterile have packaging that maintains the sterility of the accessory.
Shelf Life	The subject and predicate devices are not provided sterile; therefore, a shelf life is not applicable. The subject and predicate device accessories provided sterile demonstrate a shelf life of 2 years.
Reprocessing	The subject and predicate devices have validated reprocessing instructions.

Biocompatibility	The subject and predicate devices demonstrate the patient-contacting materials are biocompatible according to ISO 10993.
Software	The subject and predicate devices demonstrate their respective software functions as intended.
Electrical Safety and EMC	The subject and predicate devices demonstrate electrical safety and electromagnetic compatibility for use with their specified respective video processors and ultrasound scanners.
System Compatibility	The subject and predicate devices demonstrate system compatibility for use with their specified respective video processors and ultrasound scanners.
Optical Characteristics	The subject device demonstrates equivalent or better optical characteristics than the predicate device.
Substantial Equivalence Determination	Substantial equivalence was evaluated based on intended use, technological characteristics, and non-clinical testing. • The subject and predicate devices have identical intended use. • The subject and predicate devices have equivalent technological characteristics. The differences do not raise new issues of safety or effectiveness. • Sterilization, reprocessing, biocompatibility, software, EMC and electrical safety, and bench testing are provided in support of this submission. Testing results confirm the subject device is safe and effective as the predicate device, and performs as intended. Therefore, it is determined the PENTAX Medical Ultrasound Video Bronchoscope EB19-J10U is substantially equivalent to legally marketed predicate device, PENTAX Ultrasound Video Bronchoscope EB-1970UK + HI VISION PREIRUS (K131946).