January 12, 2024

PENTAX of America, Inc.
Gurvinder Singh Nanda
Senior Director Regulatory and Quality
3 Paragon Drive
Montvale, New Jersey 07645-1782

Re: K231970
Trade/Device Name: PENTAX Medical ONE Pulmo Single Use Video Bronchoscope System
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: June 27, 2023
Received: July 3, 2023

Dear Gurvinder Singh Nanda:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and
ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231970

Device Name
PENTAX Medical ONE Pulmo Single Use Video Bronchoscope System

Indications for Use *(Describe)*
PENTAX Medical Single Use Video Bronchoscope EB-S01 are sterile single use flexible endoscopes intended for use with PENTAX Medical mobile processor, therapeutic accessories, and other ancillary equipment for endoscopy and endo-therapeutic procedures within the airways and tracheobronchial tree.

PENTAX Medical Mobile Processor ONE-M is intended to be used with PENTAX Medical endoscopes and other peripheral devices for endoscopic diagnosis, treatment and video observation.

PENTAX Medical Mobile Processor Plug-in ONE-Dock is intended to be attached to the PENTAX Medical Mobile Processor to provide additional ports for hardware interface.

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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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.

1 SUBMITTER

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Date Prepared: 1/11/2024

2 SUBJECT DEVICE

PENTAX Medical is seeking clearance of a new product, PENTAX Medical ONE Pulmo Single Use Video Bronchoscope System (hereinafter "the subject device"). 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 ONE Pulmo Single Use Video Bronchoscope System.

PENTAX Medical ONE Pulmo Single Use Video Bronchoscope System, include following new devices:

- PENTAX Medical Single Use Video Bronchoscope EB11-S01
- PENTAX Medical Single Use Video Bronchoscope EB15-S01
- PENTAX Medical Mobile Processor ONE-M

- PENTAX Medical Mobile Processor Plug-In ONE-Dock

The regulatory classification of PENTAX Medical ONE Pulmo Single Use Video Bronchoscope system is identified in Table 2.1.

Table 2.1. Regulatory Classification of PENTAX Medical ONE Pulmo Single Use Video Bronchoscope System

Device Names	PENTAX Medical ONE Pulmo Single Use Bronchoscope System
Common Name	Video Bronchoscope and Video Processor
Classification Name	Bronchoscope (Flexible or Rigid) and accessories
Regulation No.	874.4680
Device Class	II
Product Code	EOQ
Classification Panel	Ear Nose & Throat

3 PREDICATE DEVICE

The predicate device is the pre-modification version of the same device, PENTAX Medical ONE Pulmo Single Use Video Bronchoscope System (K213235).

4 DEVICE DESCRIPTION

PENTAX Medical ONE Pulmo Single Use Video Bronchoscope System is intended to provide the optical visualization of the airways and tracheobronchial tree for diagnostics and therapeutic applications. The PENTAX Medical ONE Pulmo Single Use Video Bronchoscope System consist of the following three component devices:

- PENTAX Medical Single Use Video Bronchoscope EB11-S01 / EB15-S01
- PENTAX Medical Mobile Processor ONE-M
- PENTAX Medical Mobile Processor Plug-in ONE-Dock

The EB11-S01 / EB15-S01 endoscopes are connected to the ONE-M and video images captured with the bronchoscope are displayed on the touch screen of the ONE-M. The ONE-M is also connected to the Plug-in ONE-Dock, which has several interfaces, such

as an external monitor to display captured images by the bronchoscope and a connection with an external network.

More detailed device descriptions of the EB-S01 bronchoscopes, ONE-M, and Plug-in ONE-Dock mobile processors are provided in the following sub-sections.

After the 510(k) clearance in K213235 in December 2022, PENTAX Medical has implemented design changes to PENTAX Medical ONE Pulmo Single Use Bronchoscope System to enhance its performance, usability, and manufacturability. This 510(k) submission is intended to show the substantial equivalence of safety and effectiveness between the subject device (post-modification) and the predicate device.

PENTAX Medical Single Use Video Bronchoscope EB11-S01 / EB15-S01

The PENTAX Medical Single Use Video Bronchoscopes EB11-S01 and EB15-S01 are endoscopes used to provide visualization of, and therapeutic access to, the airways and tracheobronchial tree (trachea and right and left bronchus). These models are identical in all parameters and only differ in French size: 11 and 15.

The EB11-S01 / EB15-S01 bronchoscope consists of a control body, insertion portion and umbilical cable. The control body is equipped with an angulation control lever which enables operation of the distal end in up and down directions, and an instrument channel inlet. The insertion portion contains an instrument channel for a therapeutic device, a suction operation, four light guides to provide illumination, and an objective lens at the distal end.

Suction operation is made with a suction pump which is connected to a suction nipple by pushing in the suction control valve. The illumination is generated with an LED in the control body and delivered to the light guides via fiber cables. Video signals generated by the CMOS image sensor (assembled in the distal end) are transferred to the ONE-M mobile processor via communication cables. Communication and fiber cables are incorporated inside the insertion portion.

The bending section is at the tip of the insertion portion. Two steering wires for bending are assembled inside. Users can move the distal end in the intended directions by operating the angulation control lever on the control body.

The umbilical cable is equipped with a connector which enables connection with the

ONE-M mobile processor. The EB11-S01 and EB15-S01 do not contain software, they only contain electrical components to communicate with the ONE-M and those for the power supply from the mobile processor.

PENTAX Medical Mobile Processor ONE-M

In the PENTAX Medical ONE Pulmo Single Use Video Bronchoscope System, PENTAX Medical Mobile Processor ONE-M is connected with the PENTAX Medical Single Use Video Bronchoscope EB11-S01 / EB15-S01, to receive video signals from the bronchoscopes, and to display the video signals on the touch screen.

ONE-M also supplies electrical power to an LED assembled in the control body of the endoscope for the illumination and communication. In addition, the ONE-M has multiple functions similar to other PENTAX Medical video processors, such as brightness control, exposure control, color adjustment, data saving including still / video images, patient information input, as well as i-scan image processing technology. The mobile processor is not equipped with an air pump and is not capable of air / water feeding to the endoscope.

PENTAX Medical Mobile Processor Plug-in ONE-Dock

PENTAX Medical Mobile Processor Plug-in ONE-Dock is connected with the PENTAX Medical Mobile Processor ONE-M and is used for video image display with an external monitor and communication with an external network.

The external monitor is available via a DVI-D interface and the recommended PENTAX Medical 27" Radiance Ultra Display. The LAN interface enables the device to connect to an external local computer network as found in a hospital.

5 INTENDED USE AND INDICATIONS FOR USE

Intended use and Indications for use for PENTAX Medical Single Use Video Bronchoscope EB-S01

PENTAX Medical Single Use Video Bronchoscope EB-S01 are sterile single use flexible endoscopes intended for use with PENTAX Medical mobile processor, therapeutic accessories, and other ancillary equipment for endoscopy and endo-therapeutic procedures within the airways and tracheobronchial tree.

Intended use and Indications for use for PENTAX Medical Mobile Processor ONE-M

PENTAX Medical Mobile Processor ONE-M is intended to be used with PENTAX Medical endoscopes and other peripheral devices for endoscopic diagnosis, treatment and video observation.

Intended use and Indications for use for PENTAX Medical Mobile Processor Plug-in ONE-Dock

PENTAX Medical Mobile Processor Plug-in ONE-Dock is intended to be attached to the PENTAX Medical Mobile Processor to provide additional ports for hardware interface.

6 COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE

The subject device is substantially equivalent to the predicate device. The major technological differences between the two devices are as follows:

- The suction control valve has been reinforced to withstand high water supply pressure. This will enable a bronchoscopy procedure related to the water supply – Alveolar Lavage (BAL) procedure.
- Software function to activate maximum light intensity (XLUM) has been added to have the endoscope's lamp remain at a maximum intensity to see the emitted light shining through the patient's skin.
- Shelf life of the subject device has been extended to 3 years from 1 year.

The changes in the subject device 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.

The components of the subject device have the same technology and operating principles as the predicate device, as well as the same intended use. Both the subject device and the predicate device are intended for illuminating and viewing the inside of the human body. The components of the subject device consist of the same components as the predicate device, including:

- A mobile processor
- Video Bronchoscope to provide optical visualization of (via a video monitor), and therapeutic access to, the airways and tracheobronchial tree (trachea and

right and left bronchus).

The subject device is identical or enhanced to the predicate device with regards to;

- Scope working length
- Scope field of view
- Scope depth of field
- Scope tip angulation
- Software requirements

The patient contact components of both the subject and the predicate devices are biocompatible. Both subject and predicate scopes are discarded by the user after use.

7 NON-CLINICAL PERFORMANCE DATA

The PENTAX Medical ONE Pulmo Single Use Video Bronchoscope System has been successfully tested for their functions, performance, and safety as per FDA recognized consensus standards. The following performance data are provided in support of the substantial equivalence determination.

Operational Instructions for Use are provided for the endoscope.

i. Reprocessing Validation

EB-S01 scopes are provided sterile for single use and are discarded after use. Therefore, reprocessing validation is not required.

ii. Sterilization and Shelf Life

PENTAX Medical coordinated with HA2 Medizintechnik GmbH (German company) to validate the use of EO sterilization for the sterilization of the EB-S01. The scopes are provided sterile and their shelf-life is 3 years.

iii. Biocompatibility

Biocompatibility of the EB-S01 scopes on the direct and indirect contact materials was confirmed by assessing the cytotoxicity, sensitization, and intracutaneous reactivity. The risk levels of local toxicity were determined as “Acceptable” as a result of applying the risk level of local toxicity to the risk evaluation criteria.

iv. Software and Cybersecurity

Software verification and validation including cybersecurity assessments were conducted according to IEC 62304: 2006 + A1: 2015 and FDA Guidance for Industry and Staff "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.", "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" and "Post-market Management of Cybersecurity in Medical Devices."

v. *Electrical Safety and EMC*

The acceptable level of electrical safety (ES) and electromagnetic compatibility (EMC) for the subject device confirmed by the following standards:
IEC 60601-1-2:2014; IEC 60601-1:2005+CORR 1:2006+CORR 2:2007+A1:2012; and IEC 60601-2-18:2009.

vi. *System Performance*

Performance bench testing related to endoscope mechanical and durability testing were conducted. The system performance of the subject device demonstrated the equivalence to the predicate device.

vii. *Optical Performance*

Optical properties of signal to noise, sharpness, white balance, and total light intensity were measured for the subject device. All results show that this change does not affect the image quality. The subject device is substantially equivalent to the predicate device.

viii. *Animal Image Capture Study*

This change does not affect the image quality. As the subject and predicate scopes are identical, animal performance testing was not conducted.

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, PENTAX Medical concludes that the subject device is as safe and effective as the predicate device. There are no differences in indications for use and intended use between the subject and the predicate device and are therefore, substantially equivalent.

8 CONCLUSION

Accordingly, PENTAX Medical believes the PENTAX Medical ONE Pulmo Single Use Video Bronchoscope System (post-modification) is substantially equivalent to the identified predicate, PENTAX Medical believes the PENTAX Medical ONE Pulmo Single Use Video Bronchoscope System (Pre-modification) (K213235).