December 21, 2022

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

Re: K213235
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: November 18, 2022
Received: November 21, 2022

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/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,

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
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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)*
K213235

Device Name
PENTAX Medical ONE Pulmo Single Use Video Bronchoscope System

Indications for Use *(Describe)*
PENTAX Medical Single Use Video Bronchoscope EB-S01 is 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.

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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: 9/27/2021

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 1.

Table 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 for this submission is Ambu® aScope™ 4 Broncho Slim / Regular and Ambu® aView™ Monitor manufactured by Ambu A/S that was cleared by K173727.

The predicate and subject device have the same Intended use and Indications for Use, and also have similar design characteristics, and performance specifications. However, there are some differences between the subject and predicate devices. The main difference is the presence of i-Scan™ technology on the subject device although any image processing features are not equipped with the predicate device.

4 REFERENCE DEVICE

i-Scan technology has been previously cleared with other PENTAX Medical endoscopic configurations (K122470, K143727, K150618, K173679, K182846, K183691, K190805, and K200678). The PENTAX Medical endoscopic system comprised of Video Bronchoscope EB15-J10 and Video Processor EPK-i7010 (cleared by K200678) is used as the reference device.

5 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.

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.

6 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.

7 COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE

The subject device is substantially equivalent to the predicate device. The difference between the two devices are minor technological changes and presence of i-Scan technology on the subject device.

The changes in the subject device have been evaluated through performance testing including image quality animal study 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 fundamental 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 contacting components of both the subject and predicate devices are biocompatible. Both subject and the predicate scopes are discarded by the user after use.

8 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.

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 1 year. The Sterilization validation was performed in accordance with the following standards: ISO 11135: 2014, AAMI/ANSI/ISO 10993-7: 2008, ISO 11737-1: 2018, and ISO 11737-2: 2019.

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 in accordance with ISO 10993-1, 5, and 10: Biological Evaluation of Medical Devices. 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*

The system performance of the subject device demonstrated the equivalence to the predicate device.

vii. *Optical Performance*

As a part of Design Verification and Validation, optical properties of imaging and illumination performances were measured for the subject device. All results show that the optical characteristics of the subject device is equivalent to those of the predicate device.

viii. *Animal Image Capture Study*

An animal image capture study was performed as a part of optical and color performance testing. The results indicate that the subject device is able to visualize vascularity and mucosal surface for each anatomical area as well or better than the predicate device.

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 predicate device and are therefore, substantially equivalent.

9 CONCLUSION

Accordingly, PENTAX Medical believes the PENTAX Medical ONE Pulmo Single Use Video Bronchoscope System is substantially equivalent to the identified predicate, Ambu® aScope™ 4 Broncho Slim / Regular and Ambu® aView™ Monitor manufactured by Ambu A/S that was cleared by FDA in 2018 (K173727).