October 21, 2021

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

Re: K210928
Trade/Device Name: PENTAX Medical Video Bronchoscope EB11-J10
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: September 20, 2021
Received: September 22, 2021

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,

for Shu-Chen Peng
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)*
K210928

Device Name
PENTAX Medical Video Bronchoscope EB11-J10

Indications for Use *(Describe)*
The PENTAX Medical Video Bronchoscopes EB-J10 Series have been designed to be used with a PENTAX Video Processor (including Light source), documentation equipment, video monitor, endo-therapy accessories (such as biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the airways and tracheobronchial tree.

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 Video Bronchoscope EB11-J10
Traditional 510(k) Submission

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 3 Paragon Drive Montvale, New Jersey 07645-1782

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Date Prepared: 3/22/2021

Common Name: Bronchoscope
Name of the System: PENTAX Medical Video Bronchoscope EB11-J10

Regulation Number: 21 CFR Part 874.4680
Regulation Names: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ
Predicate Device: PENTAX Video Bronchoscope EB-1170K **(K131028)**

PENTAX Medical is seeking clearance of EB11-J10 Video Bronchoscope (Hereinafter "the subject device" which is a new line of Video Bronchoscopes EB-J10 Series (K200678) with the compatible PENTAX Medical Video Processors EPK-3000, EPK-i5010 (K143727), and EPK-i7010 with EB Family (K173679).
This premarket notification also 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 subject device.

The subject device has virtually the same indications for use, viewing directions, and image size as the PENTAX Medical Video Bronchoscope EB-1170K (Hereinafter "the predicate device").

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

- Introducing the subject device as a new video bronchoscope to the Video Bronchoscopes EB-J10 series.
- The subject device has a new control body design with a sterile single-use suction control valve, OF-B205.

- Due to technological advances, the optical design of the subject device has been modified. Specifically, its sensor module assembly and glass rod are different with respect to the predicate device. The optical performance of the subject and predicate devices has been confirmed to be substantially equivalent through bench testing and animal imaging study results.
- Device firmware and a charge coupled device (CCD) has been updated to reflect technological modernization with higher resolution CCD.
- The subject device is compatible with the video processor EPK-3000 in addition to compatibility with EPK-i5010, EPK-i7010.
- The subject device can be sterilized using the STERRAD 100NX® system in addition to STERRAD NX® system.

Device Description:
The subject device is used to provide visualization of, and therapeutic access to, the airways and tracheobronchial tree. There are three models of EB-J10 series: the subject device, and the previously cleared models: EB15-J10 and EB19-J10 (K200678). These models are identical in all parameters and only differ in French size: 11, 15 and 19, respectively.

The subject device is used with cleared PENTAX Video Processors (a software- controlled device). The subject device has a flexible insertion tube, a control body, and PVE connector. The PVE connector will be attached to the Video Processor and has connections for illumination, video signals, air/ water and suction.

The control body includes controls for up/ down angulation, air/ water delivery, and an accessory inlet port. The subject device contains light carrying bundles (LCB) to illuminate the body cavity, and a CCD to collect endoscopic 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 and is focused at the 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 subject device is immersible (with the use of supplied cleaning accessories) as described in the endoscope reprocessing instructions.

Intended Use /Indications for Use (EB11-J10)
The PENTAX Medical Video Bronchoscope EB11-J10 has been designed to be used with a PENTAX Video Processor (including Light source), documentation equipment, video monitor, endo-therapy accessories (such as biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the airways and tracheobronchial tree.

Compatible Video Processors
In addition to compatibility with EPK-i5010, EPK-i7010 previously cleared with other PENTAX bronchoscopes (K143727; K173679), EB11-J10 is compatible with a new processor EPK-3000 that has been previously cleared to be used with PENTAX Medical Video Bronchoscopes EB-

J10 series (K200678). EPK-3000 labeling has been revised to reflect compatibility of the processor with the EB11-J10.

Summary of Technology Characteristics:
The subject device is functionally equivalent to the predicate device, the PENTAX Medical Video Bronchoscope EB-1170K (EB Family) cleared by FDA in 2014 (K131028). The only difference between the two devices are minor technological changes.

The changes in the subject device have been evaluated through performance testing and *do not raise different issues* 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 subject device 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.

Reprocessing Validation
Simulated use testing, soil accumulation analysis, cleaning, high-level disinfection, and rinsing validation studies of the subject device and accessories were conducted and confirmed the effectiveness of reprocessing procedures.

Sterilization and Shelf Life
PENTAX Medical coordinated with Advanced Sterilization Products, Inc. to validate the use of STERRAD NX®/100NX® for the sterilization of the subject device and accessories. The subject device is not provided sterile.

Biocompatibility
Biocompatibility of the EB11-J10 scope on 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.

Software
Software verification and validation including cybersecurity assessments were conducted according to IEC 62304: 2006 and FDA Guidances for Industory 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 "*Postmarket Management of Cybersecurity in Medical Devices.*"

EMC and Electrical Safety
The acceptable level of electromagnetic compatibility (EMC) and electrical safety (ES) for the PENTAX Medical Video Bronchoscope EB11-J10 was 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, and IEC 60601-1-2:2014.

Optical Testing
As a part of Design Verification and Validation, optical properties of imaging and illumination performances were measured for subject device in conjunction with the EPK-3000, EPK- i7010, and EPK-i5010 Video Processors. All results show that the optical characteristics of the subject device is equivalent to those of the predicate device.

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 PENTAX Medical Video Bronchoscopes EB11-J10 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 devices and are therefore, substantially equivalent.
The technological differences in terms of design features, performance characteristics and constituent materials are not substantive.

Conclusion:
Accordingly, PENTAX Medical believes the PENTAX Medical Video Bronchoscopes EB11-J10 is substantially equivalent to the identified the predicate device, the PENTAX Video Bronchoscope EB-1170K, cleared by FDA in 2014 (K131028).