January 18, 2024

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

Re: K232860
Trade/Device Name: PENTAX Medical Video Processor EPK-i8020c
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: December 20, 2023
Received: December 20, 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,

Shuchen Peng -S

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)*
K232860

Device Name
PENTAX Medical EPK-i8020c Video Imaging System

Indications for Use *(Describe)*
The PENTAX Medical Video Processor EPK-i8020c is intended to be used with the PENTAX Medical camera heads, endoscopes, light sources, monitors and other ancillary equipment for gastrointestinal and pulmonary endoscopic diagnosis, treatment and video observation.
The PENTAX Medical EPK-i8020c includes a digital post-processing imaging enhancement technology (PENTAX i-ScanTM), and optical imaging enhancement technology (OE). These imaging enhancement technologies are intended to be used as an optional adjunct following traditional white light endoscopy and is not intended to replace histopathological sampling. i-Scan and OE are compatible with PENTAX Medical video gastrointestinal endoscopes and bronchoscopes.

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

Applicant: PENTAX Medical
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Date Prepared: 1/17/2024

2. SUBJECT DEVICE

Device Name	**PENTAX Medical EPK-i8020c Video Imaging System**
	PENTAX Medical Video Processor EPK-i8020c
Common Name	Endoscopic Video Processor and Light Source
Classification Name	Bronchoscope (flexible or rigid) and accessories
Regulation No.	874.4680
Device Class	II
Product Code	EOQ *
Classification Panel	Ear Nose & Throat

* The gastrointestinal use (product code: PEA) of the subject device has been cleared in K231249, and pulmonary use (product code: EOQ) is added through this submission.

The PENTAX Medical Video Processor EPK-i8020c is compatible also with the following endoscopes that have been cleared in past Premarket Notifications:

Device Name	Model name
PENTAX Medical Video Bronchoscope	EB19-J10 (K200678) EB15-J10 (K200678) EB11-J10 (K210928)
PENTAX Medical Ultrasound Video Bronchoscope	EB19-J10U (K183516 and K203166)

3. PREDICATE DEVICE

Previously cleared PENTAX Medical Video Processor and Video Scopes have been chosen as a predicate device:

Subject Device	Predicate Device
PENTAX Medical Video Processor EPK-i8020c	PENTAX Medical EPK-i7010 Video Processor with EB Family of Scopes (K173679)

4. REFERENCE DEVICE

A previously cleared PENTAX Medical Video Scopes have been chosen as a reference device:

Reference device for video scopes

Model Name	Model Number	Compatible Video processor	510(k) Clearance Number
PENTAX Medical Video Bronchoscope	EB19-J10 EB15-J10	EPK-i7010	K200678
	EB11-J10		K210928

Reference device for ultrasound video scopes

Model Name	Model Number	Compatible Video processor	Ultrasound Scanner	510(k) Clearance Number
PENTAX Medical Ultrasound Video Bronchoscope	EB19-J10U	EPK-i7010	ARIETTA 70	K183516
			ARIETTA 850	K203166

5. DEVICE DESCRIPTION

PENTAX Medical Video Processor EPK-i8020c

The PENTAX Medical Video Processor EPK-i8020c is intended to be used with PENTAX Medical endoscopes, monitors and other peripheral devices for endoscopic diagnosis, treatment, and video observation. The video processor consists of a video system, integrated light source, monitor, and ancillary equipment.

The EPK-i8020c includes a digital post-processing imaging enhancement technology (PENTAX Medical i-scan™) and an optical imaging enhancement technology (OE). These post-imaging functions are not intended to replace histopathological sampling.

The brand name "INSPIRA™" is provided for the EPK-i8020c video processor and the name is found in the instructions for use (IFU) and/or in the commercial materials such as brochures.

6. INTENDED USE AND INDICATIONS FOR USE

Intended use and Indications for use for PENTAX Medical Video Processor EPK-i8020c

The PENTAX Medical Video Processor EPK-i8020c is intended to be used with the PENTAX Medical camera heads, endoscopes, light sources, monitors and other ancillary equipment for gastrointestinal and pulmonary endoscopic diagnosis, treatment and video observation.

The PENTAX Medical EPK-i8020c includes a digital post-processing imaging enhancement technology (PENTAX i-Scan™), and optical imaging enhancement technology (OE). These imaging enhancement technologies are intended to be used as an optional adjunct following traditional white light endoscopy and is not intended to replace histopathological sampling. i-Scan and OE are compatible with PENTAX Medical video gastrointestinal endoscopes and bronchoscopes.

7. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE

The subject device is functionally equivalent to the predicate device, and the difference between the two devices are minor technological changes such as the application of a CMOS image sensor for the new endoscopes and an LED light source for the new video processor.

The changes in the subject device have been evaluated through performance testing including an image quality animal study. This study raised no 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.

The components of the subject device have the same fundamental technology and principle of operation as the predicate device. 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 video processor
- Video Bronchoscope to provide optical visualization of (via a video monitor), and therapeutic access to the trachea and bronchial tube.
- Accessories, including but not limited to a keyboard, foot switch, White Balance Adjuster, and Condenser Earth Cable

8. NON-CLINICAL PERFORMANCE DATA

The PENTAX Medical EPK-i8020c Video Imaging 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

Additional Reprocessing Validation is not required, because the subject device is not reprocessed and provided non-sterile. The reprocessing procedures of the reference devices (video bronchoscopes) have not changed since past Premarket Notifications.

ii. Sterilization and Shelf Life

Sterilization and shelf life is not required because the subject device is not

reprocessed and is not provided sterile.

iii. Biocompatibility

Additional biocompatibility is not required, because the subject device does not contain any direct or indirect patient contact components. Also, the materials of the reference devices (video bronchoscopes) have not changed since past Premarket Notifications.

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 *"Postmarket Management of Cybersecurity in Medical Devices".*

v. Electrical Safety and EMC

The acceptable level of electrical safety (ES) and electromagnetic compatibility (EMC) were 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 PENTAX Medical EPK-i8020c Video Imaging System. All results show that the optical characteristics of the subject device is equivalent to those of the predicate device and the reference 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 targeted anatomical areas as well as the predicate device and the reference 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, reprocessing and sterilization methods, 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. The technological differences in terms of design features, performance characteristics and constituent materials are not substantive.

9. CONCLUSION

Accordingly, PENTAX Medical believes the PENTAX Medical EPK-i8020c Video Imaging System does not raise any different questions of safety and effectiveness, and that the subject device of the PENTAX Medical Video Processor EPK-i8020c is substantially equivalent to the identified predicate, the PENTAX Medical Video Processor EPK-i7010, cleared by FDA in K173679.