June 3, 2025

Pentax of America, Inc
Gurvinder Singh Nanda
Senior Director, Regulatory and Quality
3 Paragon Dr
Montvale, New Jersey 07645

Re: K251127
Trade/Device Name: PENTAX Medical Video Processor (EPK-i8020c)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: PEA
Dated: April 30, 2025
Received: May 1, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251127

Please provide the device trade name(s).

PENTAX Medical Video Processor (EPK-i8020c)

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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
HOYA Corporation PENTAX Division
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Contact: Gurvinder Singh Nanda, PhD
Sr. Director, Regulatory and Quality
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Date Prepared: 04/11/2025

2. SUBJECT DEVICE

The objective of this 510(k) is to get clearance for PENTAX Medical Video Processor EPK-i8020c modified for software and instructions for use.

Device Name	PENTAX Medical Video Processor EPK-i8020c
Common Name	Gastroscope and Accessories, Flexible/Rigid
Classification Name	Endoscope and accessories
Regulation No.	876.1500
Device Class	II
Product Code	PEA
Classification Panel	Gastroenterology / Urology

3. PREDICATE DEVICE and REFERENCE DEVICE

Previously cleared PENTAX Medical Video Processor EPK-i8020c has been chosen as predicate device:

Subject Device	Predicate Device & Reference device
PENTAX Medical Video Processor EPK-i8020c	PENTAX Medical Video Processor EPK-i8020c (Predicate: K231249, Reference: K232860)

The gastrointestinal use (product code: PEA) of the subject device has been cleared in K231249 and pulmonary use (product code: EOQ) has been cleared in K232860.

4. 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.

5. INTENDED USE AND INDICATIONS FOR USE

Intended use and Indications for use for PENTAX Medical Video Processor EPKi8020c

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.

6. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE/REFERENCE DEVICES

The subject device is functionally equivalent to the predicate device, and the differences between the two devices are minor technological changes such as the software modification to add the Light Limit Mode feature, and the automatic cancellation of the OE Mode when the endoscope is removed, and related changes to the instructions for use.

The changes to the subject device were evaluated through performance testing in design validation/verification. This testing did not raise any issues regarding the safety and effectiveness of the device, as these differences do not affect 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

7. NON-CLINICAL PERFORMANCE DATA

The subject device has been successfully tested for their functions, performance, and safety. The device is not reprocessed, is not sold sterile does not contain any direct or indirect patient contact components.

The following performance data are provided in support of the substantial equivalence determination.

i. 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 *"Content of Premarket Submissions for Device Software Functions."*, *"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"*, and *"Postmarket Management of Cybersecurity in Medical Devices"*.

ii. Electrical Safety and EMC

Additional Electrical Safety and EMC evaluation are not required, because the hardware of the subject device has not changed since past Premarket Notifications.

iii. System Performance

The system performance of the subject device demonstrated the equivalence to 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) and labeling, PENTAX Medical concludes that the subject device is as safe and effective as the predicate devices. 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 significant.

8. CONCLUSION

The modified PENTAX Medical Video Processor EPK-i8020c does not pose any unique questions regarding safety and effectiveness. It is deemed to be substantially equivalent to the identified predicate: the PENTAX Medical Video Processor EPK-i8020c (K231249).