July 28, 2023

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

Re: K231249
Trade/Device Name: PENTAX Medical Video Processor EPK-i8020c,
PENTAX Medical Video Upper GI Scope EG29-i20c,
PENTAX Medical Video Colonoscope EC38-i20cL
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: PEA, FDS, FDF
Dated: April 28, 2023
Received: May 1, 2023

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,

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

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)*
K231249

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 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.

The PENTAX Medical Video Upper GI Scope EG29-i20c is intended to provide optical visualization of (via a video monitor), and therapeutic access to, the upper gastrointestinal tract. This anatomy includes the organs; tissues; and subsystems: esophagus, stomach, and duodenum.
This endoscope is introduced via the mouth when indications consistent with the need for the procedure are observed in patient populations with greater than 20 kg of body weight.

The PENTAX Medical Video Colonoscope EC38-i20cL is intended to provide optical visualization of (via a video monitor), and therapeutic access to, the lower gastrointestinal tract. This anatomy includes the organs, tissues, and subsystems: Large Bowel to the cecum, terminal ileum of the small bowel.
This endoscope is introduced via the rectum, as decided by the physician, when indications consistent with the need for the procedure are observed in patient populations with greater than 20 kg of body weight.

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

Applicant: PENTAX Medical
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Date Prepared: 7/7/2023

2. SUBJECT DEVICE

The PENTAX Medical EPK-i8020c Video Imaging System comprises of three devices: (1) the PENTAX Medical Video Processor EPK-i8020c, (2) the PENTAX Medical Video Upper GI Scope EG29-i20c, and (3) the PENTAX Medical Video Colonoscope EC38-i20cL.

Device Name	PENTAX Medical EPK-i8020c Video Imaging System		
	PENTAX Medical Video Processor EPK-i8020c	PENTAX Medical Video Upper GI Scope EG29-i20c	PENTAX Medical Video Colonoscope EC38-i20cL
Common Name	Gastroscope and Accessories, Flexible/Rigid		
Classification Name	Endoscope and accessories		
Regulation No.	876.1500		
Device Class	II		
Product Code	PEA	FDS	FDF
Classification Panel	Gastroenterology / Urology		

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

Device Name	Model name
PENTAX / PENTAX Medical Video Upper GI Scope	EG34-i10, EG29-i10, EG27-i10, EG17-J10, EG-3890TK, EG-2490K, EG29-i10c
PENTAX / PENTAX Medical Video Colonoscope	EC38-i10L, EC34-i10L, EC34-i10TL, EC-2990Li, EC-3890TLK, EC38-i10cL, EC34-i10cL
PENTAX Medical Video Duodenoscope	ED34-i10T2, ED32-i10
PENTAX Medical Ultrasound Upper GI Video Scope	EG38-J10UT, EG36-J10UR, EG34-J10U

3. PREDICATE DEVICE

A 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 Video Processor EPK-i7010 (K150618)
PENTAX Medical Video Upper GI Scope EG29-i20c	PENTAX Video Upper G.I. Scope EG29-i10 (K131902)
PENTAX Medical Video Colonoscope EC38-i20cL	PENTAX Video Colonoscope EC38-i10L (K131855)

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 Processor	EPK-i7010 (With water bottle assembly)		K191282
PENTAX Video Upper G.I. Scope	EG-3890TK	EPK-i7010	K131902
	EG27-i10		
	EG-2490K		
PENTAX Medical Video Upper GI Scope	EG34-i10		K180292
	EG17-J10		K210177
PENTAX Video Colonoscope	EC-3890TLK		K131855
	EC34-i10L		
	EC-2990Li		
PENTAX Medical Video Colonoscope	EC34-i10TL		K180285
PENTAX Medical Video Duodenoscope	ED34-i10T2		K192245
	ED32-i10		K202365
PENTAX Medical Video Upper GI Scope	EG29-i10c	EPK-i5500c	K190805
PENTAX Medical Video Colonoscope	EC38-i10cL		
	EC34-i10cL		

Reference device for ultrasound video scopes

Model Name	Model Number	Compatible Video processor	Ultrasound Scanner	510(k) Clearance Number
PENTAX Medical Ultrasound Upper GI Video Scopes	EG38-J10UT	EPK-i7010	ARIETTA 70	K200090
	EG36-J10UR		ARIETTA 850	K203166
	EG34-J10U			

Reference device for stiffness setting mechanism (EC38-i20cL)

Model Name	Manufacturer	510(k) Clearance Number
EVIS EXERA III COLONOVIDEOSCOPE CF-HQ190L	OLYMPUS MEDICAL SYSTEMS CORP.	K131780

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 supposed to be found in the instructions for use (IFU) and/or in the commercial materials such as brochures.

PETNAX Medical Video Upper GI Scope EG29-i20c

The PENTAX Medical Video Upper GI Scope EG29-i20c is designed to be used with a PENTAX Medical Video Processor, video monitor, endoscopic devices such as biopsy forceps and other ancillary equipment for optical visualization (via a video monitor) of, and/or therapeutic access to the upper gastrointestinal tract.

PENTAX Medical Video Colonoscope EC38-i20cL

The PENTAX Medical Video Colonoscope EC38-i20cL is designed to be used with a PENTAX Medical Video Processor, video monitor, endoscopic devices such as biopsy forceps and other ancillary equipment for optical visualization (via a video monitor) of, and/or therapeutic access to the lower digestive tract. The device is equipped with stiffness setting mechanism for the insertion tube. This feature enables the physician to choose the stiffness of the insertion tube, depending on the preferred level.

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 endoscopic diagnosis, treatment and video observation.

The PENTAX Medical EPK-i8020c includes a digital post-processing imaging enhancement technology (PENTAX i-Scan^{TM}), 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.

Intended use and Indications for use for PENTAX Medical Video Upper GI Scope EG29-i20c

The PENTAX Medical Video Upper GI Scope EG29-i20c is intended to provide optical visualization of (via a video monitor), and therapeutic access to, the upper gastrointestinal tract. This anatomy includes the organs; tissues; and subsystems: esophagus, stomach, and duodenum.

This endoscope is introduced via the mouth when indications consistent with the need for the procedure are observed in patient populations with greater than 20 kg of body weight.

Intended use and Indications for use for PENTAX Medical Video Colonoscope EC38-i20cL

The PENTAX Medical Video Colonoscope EC38-i20cL is intended to provide optical visualization of (via a video monitor), and therapeutic access to, the lower gastrointestinal tract. This anatomy includes the organs, tissues, and subsystems: Large Bowel to the cecum, terminal ileum of the small bowel.

This endoscope is introduced via the rectum, as decided by the physician, when indications consistent with the need for the procedure are observed in patient populations with greater than 20kg of body weight.

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 CMOS image sensor for the new endoscopes and of LED light source for the new video processor.

The changes in the subject device have been evaluated through performance testing including image quality animal study and raised 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 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 Upper GI Scope and Video Colonoscope to provide optical visualization of (via a video monitor), and therapeutic access to the Upper and Lower Gastrointestinal Tract.
- Accessories, including but not limited to a keyboard, foot switch, White Balance Adjuster, and Condenser Earth Cable

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

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

As result of the assessment, simulated use testing, cleaning, high level disinfecting and rinsing (after cleaning and after HLD) validation studies of the EG29-i20c and EC38-i20cL were conducted and confirmed the effectiveness of reprocessing procedures in accordance with FDA's 2015 Final Guidance, *"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."* Acceptance criteria were established in accordance with AAMI TIR 30: 2011 for amount of residual soil accumulation and extraction efficiency. All acceptance criteria were satisfied.

ii. Sterilization and Shelf Life

PENTAX Medical coordinated with STERIS Corporation to validate the use of System 1E liquid chemical sterilization for the sterilization of the EG29-i20c and EC38-i20cL. The device is not provided sterile; therefore, shelf-life is not applicable.

iii. Biocompatibility

Biocompatibility of the EG29-i20c and EC38-i20cL scopes on the direct and indirect contact materials was confirmed by assessing the cytotoxicity, sensitization, and intracutaneous reactivity in accordance with ISO 10993-1: 2018 "*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 *"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. Mechanical Performance

The performance of stiffness setting mechanism for the PENTAX Medical Video Colonoscope EC38-i20cL was verified by comparing to the OLYMPUS EVIS EXERA III Colonovideoscope CF-HQ190 (K131780) that is equipped with the variable stiffness feature.

viii. 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 are equivalent to those of the predicate device and the reference device.

ix. 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 can visualize vascularity and mucosal surface for each anatomical area 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, 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. 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, the PENTAX Medical Video Upper GI Scope EG29-i20c, and the PENTAX Medical Video Colonoscope EC38-i20cL is substantially equivalent to the identified predicate, the PENTAX Medical Video Processor EPK-i7010, cleared by FDA in K150618, the PENTAX Video Upper G.I. Scope EG29-i10 (K131902), and the PENTAX Video Colonoscope EC38-i10L (K131855), respectively.