November 8, 2019

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

Re: K191282
Trade/Device Name: PENTAX Medical EPK-i7010 Video Processor with GI family and PENTAX EPK-i5010 Video Processor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: PEA
Dated: October 8, 2019
Received: October 9, 2019

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,

Martha W. Betz, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191282

Device Name
PENTAX Medical EPK-i7010 Video Processor with GI Family and PENTAX EPK-i5010 Video Processor

Indications for Use *(Describe)*

The PENTAX Medical EPK-i7010 Video Processor is intended to be used with the PENTAX camera heads, endoscopes, light sources, monitors and other ancillary equipment for gastrointestinal endoscopic diagnosis, treatment and video observation.
The PENTAX Medical EPK-i7010 includes a digital post-processing imaging enhancement technology (PENTAX i-Scan™) and an 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 EPK-i5010 Video Processor is intended to be used with the PENTAX camera heads, endoscopes, light sources, monitors and other ancillary equipment for gastrointestinal endoscopic diagnosis, treatment and video observation.
The PENTAX EPK-i5010 includes PENTAX i-Scan™, a digital post-processing imaging enhancement technology. i-Scan is intended to be used as an optional adjunct following traditional white light endoscopy and is not intended to replace histopathological sampling. i-Scan is compatible with PENTAX k-series and i-series gastrointestinal videoscopes and colonovideoscopes.

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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PENTAX Medical EPK-i7010 and EPK-i5010 with GI Family of Endoscopes 510(k) Summary

I. SUBMITTER

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Phone: 201-571-2318 Ext 2318
Fax: 201-571-2340

Contact: William Goeller
Date Prepared: April 26, 2019

II. DEVICE

The purpose of this 510(k) is to obtain clearance of the PENTAX Medical EPK-i7010 Video Processor with GI family and PENTAX EPK-i5010 Video Processor for use with the PENTAX Water Bottle Assembly OS-H5.

This 510(k) captures some minor design changes that have occurred during the evolution of the product line that includes expansion of the product line to include the reusable water bottle accessory. Although the changes are believed to be minor, the 510(k) is being submitted to account for technological advances in associated the compatible devices and to ensure that FDA has the most current information concerning the PENTAX Medical video processors with GI family of scopes.

The subject devices have the same indications for use, composition of patient contact materials, viewing direction, image size, and reprocessing/sterilization method as the predicate.

Table 5.1: Regulatory Classification of PENTAX Medical Video Processors.

Device Names	**PENTAX Medical EPK-i7010 Video Processor with GI Family** **PENTAX EPK-i5010 Video Processor**
Common Name	Endoscope, Accessories, Video Post-processing for Color Enhancement
Classification Name	Endoscope and accessories
Regulation No.	876.1500
Device Class	2
Product Code	PEA
Classification Panel	Gastroenterology/ Urology

III. PREDICATE DEVICES

The predicate device for this submission, PENTAX Medical EPK-i7010 Video Processor with GI Family (K150618), is virtually identical to the subject device. It's predicate, the PENTAX EPK-i5010 Video Processor was the predicate for the EPK-i7010 submission, cleared through K122470, and it will be bundled in this submission. The subject devices differ from the predicate due to the replacement of accessory PENTAX Medical Dispo Cap Air Tubing (using a disposable water bottle) with the PENTAX Water Bottle Assembly OS-H5.

IV. DEVICE DESCRIPTION

The PENTAX Medical EPK-i7010 Video Processor and PENTAX EPK-i5010 Video Processor each consist of a video system, integrated light source, monitor, and ancillary equipment. These processors are intended for gastrointestinal endoscopic diagnostic, treatment and video observation.

The PENTAX Medical EPK-i7010 Video Processor contains two types of contrast enhancement techniques: PENTAX i-Scan technology, and optical enhancement (OE) technology. The PENTAX EPK-i5010 Video Processor contains only PENTAX i-Scan. The PENTAX i-Scan technology is a digital post-processing image enhancement technique with three modes, i-Scan 1, 2 and 3.

The table below is a list of accessories and compatible devices that are used with the EPK-i7010 and EPK-i5010 Video Processors.

Table 1: List of Accessories

Accessories Name	Model Number
PENTAX Medical Condenser Earth Cable	OL-Z4
PENTAX Foot Switch	OS-A61
PENTAX Medical Keyboard	OS-A83 OS-A79
PENTAX White Balance Adjuster	OS-A43H

**PENTAX Medical EPK-i7010 and EPK-i5010
with GI Family of Endoscopes 510(k) Summary**

PENTAX Medical Water Bottle Assembly	OS-H5
PENTAX Medical DispoCap Air (MEDIVATORS Endo SmartCap Tubing - K093665)	100160P (DispoCap Air Tubing)

Table 2: List of Compatible Devices

Compatible Devices	Manufacturer	Model name	Compatible with	
			EPK-i7010	EPK-i5010
Printer	Sony Business Solutions Corporation	UP-55MD	Y	Y
		UP-25MD	Y	---
		UP-D25MD	Y	---
		UP-21MD	---	Y
		UP-21MDA	---	Y
		UP-D23MD	---	Y
		UP-D23MDA	---	Y
External Hard Drive	Western Digital Corporation	WDBBGB0030HBK	Y	---
HD Video Recorder	Sony Business Solutions Corporation	HVO-1000MD	Y	Y
USB Flash Memory	Transcend Information, Inc.	TS32GJF600	Y	---
	SanDisk	SDCZ6-1024-A10	---	Y
LCD Monitor	(Any display devices which satisfy safety requirements and other specifications)	Safety Requirements	UL 60601-1 CAN/CSA C22.2 No.601.1 EN 60601-1	

The EPK-i7010 and EPK-i5010 are currently compatible with ENT and GI families of endoscopes.

**PENTAX Medical EPK-i7010 and EPK-i5010
with GI Family of Endoscopes 510(k) Summary**

PENTAX MEDICAL

INDICATIONS FOR USE

The PENTAX Medical EPK-i7010 Video Processor is intended to be used with the PENTAX camera heads, endoscopes, light sources, monitors and other ancillary equipment for gastrointestinal endoscopic diagnosis, treatment and video observation.

The PENTAX Medical EPK-i7010 includes a digital post-processing imaging enhancement technology (PENTAX i-Scan™) and an 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 EPK-i5010 Video Processor is intended to be used with the PENTAX camera heads, endoscopes, light sources, monitors and other ancillary equipment for gastrointestinal endoscopic diagnosis, treatment and video observation.

The PENTAX EPK-i5010 includes PENTAX i-Scan™, a digital post-processing imaging enhancement technology. i-Scan is intended to be used as an optional adjunct following traditional white light endoscopy and is not intended to replace histopathological sampling. i-Scan is compatible with PENTAX k-series and i-series gastrointestinal videoscopes and colonovideoscopes.

COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE

The subject devices are virtually identical to the predicate device. The subject devices have the same fundamental technology and operating principles of the predicate device, including the same intended use and design technological characteristics, such as Insertion Portion, Control Body and optical characteristics. The only substantive difference between the subject and predicate devices is the use of reusable PENTAX Water Bottle Assembly OS-H5 instead of Endo Smart Cap System (K093665). Since the PENTAX Water Bottle Assembly OS-H5 is initially supplied as non-sterile, an IFU for the device is provided with the EPK-i7010 and EPK-i5010 Video Processors. The IFU clearly instructs the user to clean and sterilize the water bottle daily or more frequently, depending on the patient and/or type of endoscopic procedure. However, these additional features did not affect the final product performance and did not raise any questions of safety or effectiveness as demonstrated by the biocompatibility and sterilization validation studies.

PERFORMANCE DATA

Reprocessing Validation

The PENTAX Water Bottle Assembly OS-H5 is a reusable semi-critical device (Spaulding Classification System). Since it is packaged non-sterile, it must be properly cleaned and sterilized BEFORE initial use. The OS-H5 must be subjected to an appropriate cleaning and sterilization process daily or more frequently, depending on the patient and/or type of endoscopic procedure.

The following tests have been performed for the PENTAX Water Bottle Assembly OS-H5:

- Soil Accumulation Study
- Cleaning Efficacy Study

- Rinsing Validation
- Sterilization Validation

All acceptance criteria were satisfied.

Biocompatibility

The biocompatibility of the PENTAX Water Bottle Assembly (OS-H5) (indirect patient contact materials) was confirmed by testing for Cytotoxicity, Sensitization, and Intracutaneous Reactivity. The acceptance criteria for the studies conducted conform to those dealing with surface contact devices that contact mucosal membranes for limited contact duration (< 24 hours), as depicted in ISO 10993-1, 5, and 10, "Biological evaluation of medical devices," and the FDA Guidance Document, "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing." The results of the Cytotoxicity, Sensitization, and Intracutaneous Reactivity tests conducted for PENTAX Water Bottle Assembly OS-H5, including its components/accessories, indicated that toxicity was either not detected or of negligible level. Thus, it is determined that the test results satisfy the acceptance criteria specified.

Performance Testing

The PENTAX Water Bottle Assembly OS-H5 has been tested for backflow prevention. The testing provided evidence that the contaminants from the distal end of the endoscope do not backflow into Water Bottle Assembly OS-H5. The results concluded that acceptance criteria were met, and no backflow occurred in OS-H5 under the worst-case test conditions.

In addition, flow rate and air delivery testing has been conducted with a rigid-walled OS-H5 water bottle to demonstrate its substantial equivalence to the predicate Endo Smart Cap. The results of the testing confirmed that the performance of OS-H5 is equivalent to or greater than that of the predicate Endo Smart Cap.

VIII. CONCLUSION

The subject devices are virtually identical to the predicate device. The intended use of the subject and predicate devices is identical. Any differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness.

The data submitted to support the performance and reprocessing for the PENTAX Water Bottle Assembly OS-H5 demonstrate that the device performs as intended and can be reprocessed in a safe and effective manner. The data provided in this 510(k) Premarket Notification support the equivalence of the subject and predicate devices.