DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 24, 2015

Pentax of America, Inc.
Krishna Govindarajan
Senior Manager, Regulatory Affairs
3 Paragon Drive
Montvale, NJ 07645

Re: K150618
Trade/Device Name: Pentax Medical EPK-i7010 Video Processor with GI Family
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: PEA
Dated: October 19, 2015
Received: October 20, 2015

Dear Krishna Govindarajan,

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150618

Device Name
Pentax Medical EPK-i7010 Video Processor with GI Family

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 video gastrointestinal endoscopes.

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

The following summary is provided in accordance with 21 CFR 807.92:

I. SUBMITTER

PENTAX of America, Inc.,
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3 Paragon Drive
Montvale, New Jersey 07645-1782

Phone: 201-251-2300 x 2125
Fax: 201-799-4117

Contact Person: Krishna Govindarajan
Date Prepared: October 16, 2015

II. DEVICE

Name of Device:	PENTAX Medical EPK-i7010 Video Processor with GI Family
Common or Usual Name:	Endoscopic Video Processor and Light Source
Classification Name:	Endoscopic video imaging system/component,
Classification Name:	Gastroscopes (Flexible or rigid) and accessories (21 CFR Part 876.1500)
Regulatory Class:	Class II
Product Code:	PEA

III. PREDICATE DEVICE

The PENTAX Medical EPK-i5010 Video Processor (K122470; dated April 22, 2013) is the primary predicate for this submission. This predicate device has not been subject to a design-related recall.

The OLYMPUS EVIS EXERA III Video System CV‐190 Video System Center and CLV‐190, Xenon Light Source (K112680) is the reference device for this submission.

IV. DEVICE DESCRIPTION

The PENTAX Medical EPK-i7010 video processor consists of a video system, integrated light source, monitor, and ancillary equipment. This processor is intended for 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.

White light is captured from a 300 Watt xenon lamp housed in the PENTAX Medical EPK-i7010 video processor. All visualization is done with the white light mode first. White light (BGR) illuminates the tissue and transfers the captured light through the video scope or a charged coupled device (CCD). Note that the white light visualization mode is always used first by the physician.

For i-Scan image enhancement, the modification of the combination of RGB components for each pixel occurs when the i-Scan function is turned on in the PENTAX Medical EPK-i7010 video processor. The resulting i-Scan image is then displayed on the observation monitor. For OE image enhancement, one of the two optical filters corresponding to Mode1 and Mode2 are inserted into illumination light path when the OE function is turned on in the PENTAX Medical EPK-i7010 video processor. The resulting OE image is then displayed on the observation monitor.

The table below are the list of accessories and compatible devices that are used with the EPK-i7010 Video Processor.

Table 1: List of Accessories

Accessories Name	Intended Use	Model Number
PENTAX Condenser Earth Cable	Condenser earth cable OL-Z4 is intended to reduce high- frequency noise which is generated during high- frequency electro cautery device use together with Pentax endoscopes.	OL-Z4
PENTAX Foot Switch	Foot Switch OS-A61 is used to remotely control processor functions.	OS-A61
PENTAX Keyboard	PENTAX medical keyboard OS-A83 is intended to be used with compatible PENTAX video processor EPK-i7010. OS-A83 keyboard for input data entry and operate the video processor by assigned function keys.	OS-A83
PENTAX White Balance Adjuster	White Balance Adjuster OS- A43H is a white tube used as the object of white balance feature.	OS-A43H
PENTAX Medical DispoCap Air (MEDIVATORS Endo SmartCap Tubing – K093665)	PENTAX Medical DispoCap tubing is intended to be used with an air or CO2 source along with a sterile water source to supply air or CO2 and sterile water to an gastrointestinal endoscope during endoscopic procedures.	100160P (DispoCap Air Tubing)

Table 2: List of Compatible Devices

Compatible Devices	Manufacturer	Model Name
Printer	Sony Business Solutions Corporation	UP-55MD
	Sony Business Solutions Corporation	UP-25MD
External Hard Drive	Western Digital Corporation	WDBAAU0020HBK
HD Video Recorder	Sony Business Solutions Corporation	HVO-1000MD
USB Flash Memory	Transcend Information Inc.	TS32GJF600
LCD Monitor	NDS Surgical Imaging	26”Radiance G2 HB

The EPK-i7010 is compatible with PENTAX video gastrointestinal endoscopes.

V. 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The PENTAX Medical EPK-i7010 Video Processor with GI Family (subject device) has the same intended use, design, fundamental operating principle, and scientific technology as the PENTAX Medical EPK-i5010 Video Processor (K122470; dated April 22, 2013) (primary predicate device). Both devices also have the same indications for use; namely, for use in gastrointestinal endoscopic diagnosis, treatment and video observation in the upper and lower gastrointestinal anatomy. The devices differ slightly with regard to design and technological characteristics. Performance data, specifically optical bench and animal testing, is provided to support substantial equivalence of the devices. The EPK-i7010 Video Processor includes additional functionalities that are not available in the EPK-i5010, such as Optical Enhancement (OE) technology, Digital output, Electrical Zoom, Front Operation Panel, Language, Input method, Freeze Scan, Contrast, Twin Mode, and several additional video image display options. However, these additional functionalities do not affect the final product performance and did not raise any questions of safety or effectiveness as demonstrated by the software verification and validation testing.

The PENTAX Medical EPK-i7010 Video Processor with GI Family (subject device) has the same intended use and fundamental operating principle including the Optical Enhancement (OE) technology, compared to the commercially available The OLYMPUS EVIS EXERA III Video System CV‐190 Video System Center and CLV‐190, Xenon Light Source (K112680) (reference device). The devices differ slightly with regard to design and technological characteristics. Performance data, specifically optical bench and animal testing, is provided to support substantial equivalence of the devices.

VII. PERFORMANCE DATA

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

Electrical Safety and electromagnetic compatibility (EMC)

The acceptable level of Electromagnetic Compatibility (EMC) and Electrical Safety (ES) for the PENTAX Medical EPK-i7010 Video Processor with GI Family was confirmed by testing in accordance with the following standards:

1. IEC 60601-1:2005+A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2:Edition 3:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
3. IEC 60601-1-6 Edition 3.0:2010, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
4. IEC 60601-2-18 Edition 3.0:2009, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software is classified as CLASS B under the Software Safety Classification per IEC 62304:2006, Medical device software- Software life cycle processes) and the software level of concern is "Moderate" based on the FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

All testing of the software was conducted in compliance with the following standards:

1. ISO 14971 Second Edition:2007, Medical devices - Application of risk management to medical devices
2. IEC 62304 First Edition:2006, Medical device software - Software life cycle processes
3. IEC 62471 First Edition:2006, Photobiological safety of lamps and lamp systems

Optical Performance Testing (Bench and Animal non-clinical testing)

Animal Study
A library of images [white light endoscopic (WLE), PENTAX Optical Enhancement (OE), and Olympus Narrow Band Imaging (NBI)] were obtained from the porcine gastrointestinal mucosa. The images were used for image evaluation and quantitative data analysis.

Bench Testing
Optical Enhancement (OE) and Artifact Analysis were performed with the images from the porcine gastrointestinal location that were gathered using two PENTAX Medical gastrointestinal endoscopes, one high definition and one standard definition, along with an Olympus gastrointestinal endoscopes. In addition, PENTAX Medical and Olympus gastrointestinal endoscopes were compared and the effects of processing features on Limited Resolution optical bench testing were conducted.

The animal and optical bench test image data gathered with gastrointestinal endoscopes establish the equivalence of the subject and predicate device.

VIII. CONCLUSIONS

The data submitted support the safety of the device and the hardware and software verification and validation demonstrate that the PENTAX Medical EPK-i7010 Video Processor performs as intended in the specified use conditions. The optical data analysis demonstrate that the PENTAX Medical EPK-i7010 Video Processor performs comparably to the predicate device that is currently marketed for the same indication for use.