July 3, 2018

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

Re: K173679
Trade/Device Name: PENTAX Medical EPK-i7010 Video Processor with EB Family of Scopes
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: June 1, 2018
Received: June 4, 2018

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. 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Michael J. Ryan -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173679

Device Name
PENTAX Medical EPK-i7010 Video Processor with EB Family of Scopes

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 bronchoscopic 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 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

I. SUBMITTER

PENTAX of America, Inc.,
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Phone: 201-571-2318
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Contact: William Goeller
Date Prepared: November 8, 2017

II. DEVICE

Device Name	PENTAX Medical EPK-i7010 Video Processor with EB Family of Scopes
Common Name	Endoscopic Video Processor and Light Source
Classification Name	Endoscopic video imaging system/component
Regulation No.	21 CFR Part 874.4680
Regulation Name	Bronchoscopes (Flexible or Rigid) and accessories
Device Class	2

III. PREDICATE DEVICES

The PENTAX Medical EPK-i5010 Video Processor with EB Family (K143727) is the predicate device for this 510(k) Premarket Notification as the processors have the same intended use and the minor technology differences do not raise new issues of safety and effectiveness.

The PENTAX Medical EPK-i7010 Video Processor with GI Family (K150618) is utilized as a Reference Device for this 510(k) Premarket Notification as the processor is identical to the subject device.

IV. DEVICE DESCRIPTION

The purpose of this 510(k) is to expand the indications for the PENTAX Medical EPK-i7010 Video Processor with GI Family (K150618) to include the PENTAX Video Bronchoscopes, EB Family (k131028): EB-1970TK, EB-1170K, EB-1570K, EB-1970K, EB-1575K, EB-1975K, EB -1990i).

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 bronchoscopic diagnosis, treatment and video observation.

The PENTAX Medical EPK-i7010 Video Processor contains PENTAX i-Scan and Optical Enhancement (OE) technologies.

The PENTAX i-Scan technology is a digital filter-based image enhancement technique with three modes, i-Scan 1, 2, and 3. PENTAX i-Scan™ is intended to give the user an enhanced view of the texture of the mucosal surface and blood vessels.

In addition to i-Scan, OE is intended to provide alternative methods to improve blood vessel visibility by using band limited light illumination source. The OE technology emphasizes mucosal microvasculature and fine mucosal structures on the bronchial surface.

The following accessories are provided for use with the PENTAX Medical EPK-i7010 Video Processor and EB Family of Scopes:

- Keyboard - input device for the video processor.
- Foot Switch - used to remotely control processor functions.
- White Balance Adjuster - used as the object of white balance feature.
- Condenser Earth Cable - used to reduce high-frequency noise generated during high-frequency electro cautery device use with Pentax 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 bronchoscopic 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 bronchoscopes.

COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE

There are no differences between the subject and predicate devices with regard to intended use. Both subject and predicate devices are intended for illuminating the inside of the human body.

The subject and predicate video processors have virtually identical indications for use and are substantially equivalent with regard to design, technological characteristics, energy used, performance, safety, and effectiveness.
The subject and reference processors are identical with regard to design, technological characteristics, energy used, performance, safety, and effectiveness. The sole difference is the addition of a bronchoscopic indication.
There are no significant differences in technical characteristics that raise new questions of safety and effectiveness. The data provided in this 510(k) Premarket Notification support the equivalence of the subject and predicate devices.

VI. PERFORMANCE DATA

The following performance data are provided to support the equivalence of the subject and predicate devices.

a. Electrical Safety and Electromagnetic Compatibility (EMC)

The PENTAX Medical EPK-i7010 Video Processor and PENTAX Medical EB Family of Scopes were tested and comply with the following standards for electrical safety and EMC.

- CISPR 11:2009, A1:2010 Group 1 Class B
- IEC 61000-4-2:2008; IEC 61000-4-3:2006, A1:2007, A2:2010, IEC 61000-4-4:2012; IEC 61000-4-5:2005; IEC 61000-4-6:2013; IEC 61000-4-8:2009; IEC 61000-4-11:2004; IEC 61000-3-2:2014; IEC 61000-3-3:2013
- IEC 60601-1-2:2007; IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+AM1:2012; IEC 60601-2-18:2009
- ANSI/AAMI ES60601-1:2005 + A2:2010 + A1:2012
- IEC 62304:2006
- CAN/CSA-C22.2 NO. 60601-2-18:11

b. Software Verification and Validation

Software verification and validation testing was 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 for this device is considered a "moderate" level of concern based on the FDA guidance.

c. Performance Testing

Bench Testing

Optical testing was performed with the PENTAX Medical EPK-i7010 Video Processor with EB Family of Scopes, as well as PENTAX Medical EKP-i5010 with EB Family. Testing consisted of Signal to Noise, Color (IEE), Resolution, Modulation Transfer Function, Distortion, Light Distribution, Spectral Distribution, Total Luminous Flux, and Photobiological Safety testing. It was concluded that the performance of the subject and predicate devices are equivalent.

Animal Testing

PENTAX Medical performed a porcine animal study to show the similarity of visual experience of the PENTAX Medical EPK-i7010 Video Processor with EB Family of Scopes (subject) in comparison to PENTAX Medical EKP-i5010 Video Processor with EB Family (predicate).

A library of images was captured to show visual experience for both processors for white light images (WLE) and i-Scan images. Images of the pig larynx demonstrate similar visual experience between scopes.

VIII. CONCLUSION

The data submitted in support of the safety of the device and the hardware and software verification and validation demonstrate that the PENTAX Medical EPK-i7010 Video Processor with EB Family of Scopes performs as intended in the specified use conditions. The optical data analysis demonstrates the equivalence of the PENTAX Medical EPK-i7010 Video Processor with EB Family of Scopes to the predicate device. Furthermore, a porcine animal study shows the similarity of visual experience with PENTAX Medical EPK-i7010 Video Processor with EB Family of Scopes in comparison with the predicate device.

The subject and predicate devices have the same intended use, and there are no significant differences in technical characteristics that raise different questions of safety and effectiveness. The data provided in this 510(k) Premarket Notification support the equivalence of the subject and predicate devices.