January 9, 2019

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

Re: K182846
Trade/Device Name: PENTAX Medical EPK-3000 Video Imaging System
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOB, PEA, EQL, OUG
Dated: December 7, 2018
Received: December 10, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Srinivas Nandkumar -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)*
K182846

Device Name
PENTAX Medical EPK-3000 Video Imaging System

Indications for Use *(Describe)*

PENTAX Medical EPK-3000 Video Imaging System consists of PENTAX Medical VIDEO PROCESSOR EPK-3000, PENTAX Medical Video Naso-Pharyngo-Laryngoscope VNL-J10 Series, PENTAX Medical Digital Video Capture Modules, PENTAX Medical Laryngeal Strobe, and other ancillary equipment.

1) PENTAX Medical Video Processor EPK-3000

The PENTAX Medical EPK-3000 Video Processor is intended to be used with the PENTAX VNL8-J10, VNL11-J10, and VNL15-J10 endoscopes, PENTAX Medical Laryngeal Strobe, video monitors and other ancillary equipment for ENT endoscopic observation and nasopharyngo-laryngoscopic (ENT) diagnosis, treatment and video observation with or without stroboscopy.

The PENTAX Medical EPK-3000 Video Processor 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.

2) PENTAX Medical Video Naso-Pharyngo-Laryngoscope VNL-J10 Series

The PENTAX Medical Video Naso-Pharyngo-Laryngoscope VNL-J10 Series (VNL8-J10, VNL11-J10 and VNL15-J10) are intended to be used with a PENTAX EPK-3000 Video Processor, PENTAX Medical Laryngeal Strobe, documentation equipment, video monitor, endoscopic device and other ancillary equipment for optical visualization (via a video monitor) of, and, for VNL15-J10 only, therapeutic access to, nasal, pharyngeal, laryngeal and the upper airway anatomy.

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-3000 Video Imaging System
Special 510(k)

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.

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Date Prepared: October 5, 2018

Common Name: Endoscope, Accessories, Image Post-Processing For Color Enhancement/ Naso-Pharyngo-Laryngoscope / Laryngostroboscope / Video Capture Modules
Name of the System: PENTAX Medical EPK-3000 Video Imaging System
Pentax Medical Video Processor EPK -3000 with PENTAX Medical Video Naso-Pharyngo-Laryngoscope VNL-J10 (K172156) with PENTAX Medical Laryngeal Strobe 9400 (listed class 1 device), with PENTAX Medical Digital Video Capture Modules 9310HD /9372HD (listed class 1 devices)

Regulation Number:
21 CFR Part 876.1500
21 CFR Part 874.4760
21 CFR Part 874.4750
21 CFR Part 880.6310
Regulation Names:
Endoscope and accessories
Nasopharyngoscope (flexible or rigid) and accessories
Laryngostroboscope
Medical device data system

Regulatory Class: Class II
Product Code: PEA, EOB, EQL, OUG

Predicate Device: PENTAX Medical EPK-3000 Video Imaging System (K172156)

The proposed PENTAX modification is the combination of interoperable medical devices that will be used as one system. All the devices have been previously cleared and for the Class I devices, listed with FDA.

The primary components of the new system include the following:

- PENTAX Medical Video Processor EPK-3000
- PENTAX Medical Video Naso-Pharyngo-Laryngoscope VNL-J10 Series (VNL8-J10, VNL11-J10, VNL15-J10)
- PENTAX Medical Laryngeal Strobe 9400
- PENTAX Medical Digital Video Capture Modules (two models are available: 9310HD/9372HD)

For the above listed system components the design was not altered following this combined end-to-end system configuration. The 510(k) is being submitted to account for the new system interoperability through the conduct of appropriate verification, validation and risk management activities; and modifying labeling by specifying the relevant functional, performance, and interface characteristics.

The combined PENTAX Medical EPK-3000 Video Imaging System has the same fundamental technology and operating principles as the predicate device, as well as the same intended use. Both the PENTAX Medical EPK-3000 Video Imaging System and the predicate device are intended for illuminating and viewing the inside of the human body.

The indications for use were slightly modified by specifying "PENTAX Medical Laryngeal Strobe" instead of the "light sources (including strobe)" cited in the predicate's indications for use. "PENTAX Medical Digital Video Capture Modules" were also added to the Indications for Use, to specify "documentation equipment" mentioned in the predicate's indications for use.

The main differences between the subject devices and predicate devices are as follows:

- Adding a Laryngeal Stroboscope 9400 that allows observation of the glottic action of the vocal folds to the system configuration;
- Adding a High-Definition Digital Video Capture Module (9310HD and 9372HD) to electronically record, display, transfer, and store digital video data of laryngeal or pharyngeal structures, and audio data, for medical and pedagogical applications.

Device Description:

PENTAX Medical EPK-3000 Video Imaging System is used for ENT endoscopic observation and nasopharyngo-laryngoscopic (ENT) diagnosis, treatment, and video observation.
The System functions by receiving image signals from the image sensor in an endoscope, which are processed within a video processor and then output to a monitor. Brightness, color balance, and other properties of the displayed images can be adjusted using the buttons on the system's control panel. The light from a xenon lamp at the distal end of the endoscope illuminates the body cavities of the patient through the endoscope connected to the video processor.
The primary components of the system include the following:

- PENTAX Medical Video Processor EPK-3000
- PENTAX Medical Video Naso-Pharyngo-Laryngoscope VNL-J10 Series (VNL-J10 Series)
- PENTAX Medical Laryngeal Strobe 9400
- PENTAX Medical Digital Video Capture Modules (two models are available: 9310HD/9372HD)

The PENTAX Medical EPK-3000 Video Imaging System is provided with the following accessories:

- 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
• Inlet Seal - prevents suctioned fluid from coming out of the instrument Channel Inlet during the use of suction function. During the reprocessing, it seals the instrument Channel Inlet in order to full the chemical solution inside the channel
• Bite Block - prevents patients from biting the endoscope insertion tube during an endoscopic examination
• Suction Control Valve - intended to control suction

Additional accessories for reprocessing are provided with the device. These include Cleaning Adapter, Soaking Cap, Ventilation Cap, Cleaning Brush Kits, Endoscope Cleaning Brush Kits, and replacement O- Rings.

The PENTAX Medical Video Processor EPK-3000 is intended to be used with the PENTAX compatible endoscopes, light sources (including strobe), vide monitors and other ancillary equipment for ENT endoscopic observation and nasopharyngo-laryngoscopic (ENT) diagnosis, treatment, and video observation with or without stroboscopy.

PENTAX Medical Video Processor EPK-3000 functions with the PENTAX i-Scan technology, 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.

White light is captured from a 150-Watt xenon lamp housed in the EPK-3000 Video Processor. All visualization is done with the white light mode first. White light 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. The modification of the combination of red, green, blue (RGB) components for each pixel occurs when the i-Scan function is turned on in the EPK-3000 Video Processor. The resulting i- Scan image is then displayed on the observation monitor.
The PENTAX Medical Video Processor EPK-3000 is compatible with PENTAX Medical Video Naso-Pharyngo-Laryngoscope VNL-J10 Series. The PENTAX Medical Video Naso-Pharyngo-Laryngoscope VNL-J10 Series are intended to be used with a PENTAX Video Processor (including Light source), documentation equipment, video monitor, and other ancillary equipment for optical visualization (via a video monitor) of, and/or therapeutic access to, nasal, pharyngeal, laryngeal and the upper airway anatomy. Three scopes are included in the VNL-J10 Series of scopes that is the subject of this submission: VNL8-J10, VNL11-J10, and VNL15-J10.

The VNL-J10 Series endoscopes are inserted transorally or transnasally to visualize subjects under illumination transmitted from a video processor with a solid-state image sensor located at the distal end of the endoscope, and provide images of the target anatomy on the video monitor. The endoscopes are flexible which allows the insertion portion to shape according to the body cavity. They are also composed of an Insertion Portion, Control Body, PVE Connector, and Light Guide Plug.
The VNL15-J10 can be used with endoscopic devices, each of which is introduced from the instrument channel inlet of the control body. Additionally, suctioning from the instrument channel at the distal end of the endoscope by pressing the suction control valve is available with this model. The VNL8-J10 and the VNL11-J10 do not have an instrument channel.

Intended Use / Indications for use

PENTAX Medical EPK-3000 Video Imaging System consists of PENTAX Medical VIDEO PROCESSOR EPK-3000, PENTAX Medical Video Naso-Pharyngo-Laryngoscope VNL-J10 Series, PENTAX Medical Digital Video Capture Modules, PENTAX Medical Laryngeal Strobe, and other ancillary equipment.

1) PENTAX Medical Video Processor EPK-3000

The PENTAX Medical EPK-3000 Video Processor is intended to be used with the PENTAX VNL8-J10, VNL11-J10, and VNL15-J10 endoscopes, PENTAX Medical Laryngeal Strobe, video monitors and other ancillary equipment for ENT endoscopic observation and nasopharyngo-laryngoscopic (ENT) diagnosis, treatment and video observation with or without stroboscopy.

The PENTAX Medical EPK-3000 Video Processor 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.

2) PENTAX Medical Video Naso-Pharyngo-Laryngoscope VNL-J10 Series

The PENTAX Medical Video Naso-Pharyngo-Laryngoscope VNL-J10 Series (VNL8-J10, VNL11-J10 and VNL15-J10) are intended to be used with a PENTAX EPK-3000 Video Processor, PENTAX Medical Laryngeal Strobe, documentation equipment, video monitor, endoscopic device and other ancillary equipment for optical visualization (via a video monitor) of, and, for VNL15-J10 only, therapeutic access to, nasal, pharyngeal, laryngeal and the upper airway anatomy.

Summary of Technology Characteristics:

The PENTAX Medical EPK-3000 Video Imaging System is functionally equivalent to its predicate device, the PENTAX Medical EPK-3000 Video Imaging System cleared by FDA in 2018 (K172156). The only difference between the two devices is that two additional devices have been added to the subject system configuration, namely:

- Laryngeal Stroboscope 9400 for observation of the glottic action of the vocal folds
- High-Definition Digital Video Capture Module (9310HD and 9372HD) for electronic recording, displaying, transferring, and storing of digital video and audio data of laryngeal or pharyngeal structures

The modified system configuration has been evaluated through performance testing and raise 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.

Non-Clinical Performance Data

The PENTAX Medical EPK-3000 Video Imaging System has been successfully tested for its functions, performance and safety as per FDA recognized consensus standards. The following performance data are provided in support of the substantial equivalence determination.

System Interoperability Testing

Interoperability verification and validation testing of the end-to-end system has been informed by the FDA Guidance document “Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices” and has been verified and validated through Design Verification testing.

The acceptance criteria have been satisfied for all tests.

Cybersecurity risks have been assessed and mitigated according to the FDA Guidances for Industry and Staff "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" issued October 2, 2014, and "Postmarket Management of Cybersecurity in Medical Devices." issued December 28, 2016.

EMC and Electrical Safety
The acceptable level of electromagnetic compatibility (EMC) and electrical safety (ES) for the PENTAX Medical EPK-3000 Video Imaging System were confirmed by the following standards:
IEC 60601-1-2:2007; ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012, and A2:2010/(R)2012.

Photobiological Safety of Lamps
The photobiological safety of the Pentax Medical Laryngeal Strobe 9400 lamp systems was evaluated in accordance with *IEC62471, Photobiological Safety of Lamps and Lamp Systems*.
It was determined that the lamp classification group was an Exempt risk group.

Substantial Equivalence Discussion:
The subject and predicate devices have the same intended use fundamental technology and there are no significant differences that raise different questions of safety and effectiveness. The differences in terms of design features, performance characteristics and constituent materials are not substantive.

Conclusion:
Accordingly, PENTAX Medical believes the PENTAX Medical EPK-3000 Video Imaging System is substantially equivalent to the identified predicate, the PENTAX Medical EPK-3000 Video Imaging System, cleared by FDA in 2018.