April 5, 2018

Pentax Medical
James W. Monroe
Director, Regulatory Affairs
3 Paragon Drive
Montvale, NJ 07645

Re: K172156
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
Dated: March 2, 2018
Received: March 5, 2018

Dear James W. Monroe:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Eric A. Mann -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)*
K172156

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, and other ancillary equipment.

1. PENTAX Medical VIDEO PROCESSOR EPK-3000

The PENTAX Medical VIDEO PROCESSOR EPK-3000 is intended to be used with the PENTAX VNL8-J10, VNL11-J10, and VNL15-J10 endoscopes, light sources (including strobe), video monitors and other ancillary equipment for ENT endoscopic observation and nasopharyngo-laryngoscopic (ENT) diagnosis, treatment and video observation.

The PENTAX Medical VIDEO PROCESSOR EPK-3000 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 (including Light source), 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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510(k) Summary

I. SUBMITTER

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Contact: James W. Monroe
Date Prepared: July 14, 2017
Date Revised: March 02, 2018

II. DEVICE

The PENTAX Medical EPK-3000 Video Imaging System is composed of two parts: (1) the PENTAX Medical Video Processor EPK-3000, and (2) the PENTAX Medical Video Naso-Pharyngo- Laryngoscope VNL-J10 Series.

Device Name	**PENTAX Medical EPK-3000 Video Imaging System**	
	PENTAX Medical Video Processor EPK-3000	**PENTAX Medical Video Naso-Pharyngo-Laryngoscope VNL-J10 Series**
Common Name	Endoscope, Accessories, Image Post-Processing For Color Enhancement	Naso-Pharyngo-Laryngoscope
Classification Name	Endoscope and accessories	Nasopharyngoscope (flexible or rigid) and accessories
Regulation No.	876.1500	874.4760
Device Class	2	2
Product Code	PEA	EOB

III. PREDICATE DEVICES

A previously cleared PENTAX Medical ENT Imaging System has been chosen as a predicate device:

Subject Device	Predicate Device
PENTAX Medical EPK-3000 Video Imaging System - PENTAX Medical Video Naso-Pharyngo-Laryngoscope VNL8-J10, VNL11-J10, and VNL15-J10 and PENTAX Medical Video Processor, EPK-3000	**PENTAX Medical ENT Video Imaging System (K162151)** - PENTAX Medical Video-Naso-Pharyngo-Laryngoscope VNL-1570STK and PENTAX Medical Video Processor, EPK-i5010

IV. 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 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)

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.

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, endoscopic device 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.

V. 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, and other ancillary equipment.

1. PENTAX Medical Video Processor EPK-3000

The PENTAX Medical Video Processor EPK-3000 is intended to be used with the PENTAX VNL8-J10, VNL11-J10, and VNL15-J10 endoscopes, light sources (including strobe), video monitors and other ancillary equipment for ENT endoscopic observation and nasopharyngo-laryngoscopic (ENT) diagnosis, treatment and video observation.

The PENTAX Medical Video Processor EPK-3000 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 (including Light source), 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.

VI. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE

The components of the PENTAX Medical EPK-3000 Video Imaging System have the same fundamental technology and operating principles as the predicate devices, 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 components of the PENTAX Medical EPK-3000 Video Imaging System consist of the same components as the predicate devices, including:

- A video processor, including integrated light source
- Naso-Pharyngo-Laryngoscopes to observe the nasal, pharyngeal, laryngeal and the upper airway anatomy
- Accessories, including by not limited to a keyboard, foot switch, White Balance Adjuster, and Condenser Earth Cable

The subject and predicate devices are identical or equivalent with regard to

- Scope working length
- Scope field of view depth of field
- Scope tip angulation
- Software requirements
- Power requirements
- Illumination
- Noise reduction
- Surface, contrast, and tone enhancement

The patient contacting components of both the subject and predicate devices are biocompatible. Both subject and the predicate scopes are reprocessed by the user. Side-by-side bench and clinical usability tests were conducted that have also shown the EPK-3000 Video Imaging System to be substantially equivalent to the predicate device.

The technological differences between the subject and predicate devices include

- Minor differences in specifications between subject and predicate device components

The minor differences between the subject and predicate devices do not impact the intended use and do not raise different questions of safety and effectiveness. Performance data, specifically optical bench

and animal testing, is provided to support substantial equivalence of the subject and predicate devices.

VII. PERFORMANCE DATA

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

a. Reprocessing Validation

The following testing has been performed for the VNL-J10 Series scopes:

- Simulated Use Testing
- Soil Accumulation
- Cleaning Efficacy
- High Level Disinfection (HLD) Efficacy
- Rinsing Validation
- STERRAD® NX® Efficacy Study after Cleaning and HLD
- STERRAD® 100NX® Efficacy Study after Cleaning

All acceptance criteria were satisfied.

b. Biocompatibility

The biocompatibility evaluation of the patient contacting materials of the PENTAX Medical EPK-3000 Video Imaging System was conducted in accordance with the "FDA Blue Book Memorandum #G95-1: Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (May 1, 1995)", and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The system is considered a surface device with mucosal contact of limited duration (<24 hours).

The following tests were conducted with passing results:

- Cytotoxicity Test
- Sensitization Test
- Intracutaneous Reactivity Test

c. Electrical Safety and Electromagnetic Compatibility (EMC)

The PENTAX Medical Video Processor EPK-3000 and PENTAX Medical Video Naso-Pharyngo-Laryngoscope VNL-J10 Series were tested and comply with the following standards for electrical safety and EMC.

- IEC 60601-1, IEC 60601-2-18
- IEC 61000-3-2 and IEC 61000-3-3, IEC 61000-4-2 - IEC 61000-4-6, IEC 61000-4-8, IEC 61000-4-11
- IEC 62304:2006
- CISPR 11:2009

d. 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.

e. Performance Testing

Bench Testing

Optical testing was performed to compare the PENTAX Medical EPK-3000 Video Imaging System with the PENTAX Medical model, VNL-1570STK (K162151). 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.

Verification and validation testing was also conducted, including endoscope operability, image quality, endotherapy device insertability, and single-use suction valve testing.

Clinical Usability Testing

PENTAX Medical performed a non-significant risk clinical study with IRB approval to show comparative data with the subject device, PENTAX Medical Video Processor EPK-3000 used in conjunction with PENTAX VNL8-J10, VNL11-J10, and VNL15-J10 Naso-pharyngo-laryngoscopes (subject) in comparison to the PENTAX Medical PENTAX model, VNL-1570STK and EPK-i5010 (K162151), predicate device. A library of images was captured to display vascular structure and/or mucosal surfaces from subject device and predicate device for both white light images (WLE) and i-Scan images. These images were evaluated by experienced ENT physicians and subject devices were evaluated as having equivalent ability to visualize vascular structure and/or mucosal surface to for both white light images (WLE) and i-Scan images, as compared to the predicate device.

VIII. CONCLUSION

The data submitted support the safety of the device and the hardware and software verification and validation demonstrate that the PENTAX Medical EPK-3000 Video Imaging System performs as intended in the specified use conditions. The optical data analysis demonstrates the substantial equivalence of the PENTAX Medical EPK-3000 Video Imaging System to the predicate device. Furthermore, a non-significant risk clinical study with IRB approval shows subject device has equivalent ability to visualize vascular structure and/or mucosal surface to for both white light images (WLE) and i-Scan images, as compared to 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.