DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 20, 2017

Pentax of America, Inc.
Mr. Krishna Govindarajan
Senior Manager, Regulatory Affairs
3 Paragon Drive
Montvale, NJ 07645-1782

Re: K162151
Trade/Device Name: Pentax Medical Ent Video Imaging System
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: July 29, 2016
Received: August 2, 2016

Dear Mr. 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,

Eric A. Mann -S

for Malvina 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162151

Device Name
PENTAX Medical ENT Video Imaging System

Indications for Use *(Describe)*

PENTAX Medical ENT Video Imaging System consists of PENTAX Medical Video Naso-Pharyngo-Laryngoscope, PENTAX Medical Video Processor and other ancillary equipment.

1. PENTAX Medical Video Naso-Pharyngo-Laryngoscope

The PENTAX Medical Video Naso-Pharyngo-Laryngoscopes (VNL-1570STK) is designed to be used with a PENTAX Medical video processor, light source, documentation equipment, display monitor, endoscopic accessories, and other ancillary equipment and intended to provide optical visualization (via a video monitor) of, and therapeutic access to, nasal, pharyngeal, laryngeal and the upper airway anatomy.

2. PENTAX Medical Video Processor

The PENTAX Medical Video Processor (EPK-i5010) is intended to be used with the PENTAX Medical camera heads, compatible endoscopes, light sources, monitors and other ancillary equipment for ENT endoscopic observation and diagnosis, and naso-pharyngo- laryngoscopic diagnosis, and treatment.

The PENTAX Medical EPK-i5010 includes PENTAX i-Scan™, a digital, post-processing imaging enhancement technology.

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.

K162151

510(k) Summary

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

I. SUBMITTER

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

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

Contact Person: Krishna Govindarajan
Date Prepared: September 28, 2016

II. DEVICE / SYSTEM

Trade/Device Name: **PENTAX Medical ENT Video Imaging System**

Name of Device:	PENTAX Medical Video Naso-Pharyngo-Laryngoscopes (VNL-1570STK)
Common or Usual Name:	Nasopharyngoscope (flexible or rigid)
Classification Name:	Nasopharyngoscope (flexible or rigid) and accessories (21 CFR Part 874.4760)
Regulatory Class:	Class II
Product Code:	EOB

Name of Device:	PENTAX Medical Video Processor (EPK-i5010)
Common or Usual Name:	Endoscopic Video Processor and Light Source
Classification Name:	Nasopharyngoscope (flexible or rigid) and accessories (21 CFR Part 874.4760)
Regulatory Class:	Class II
Product Code:	EOB and PEA

III. PREDICATE and REFERENCE DEVICE

Trade/Device Name: OLYMPUS EVIS EXERA 180 System
The OLYMPUS EVIS EXERA II 180 System (K061313) is the primary predicate for this submission.

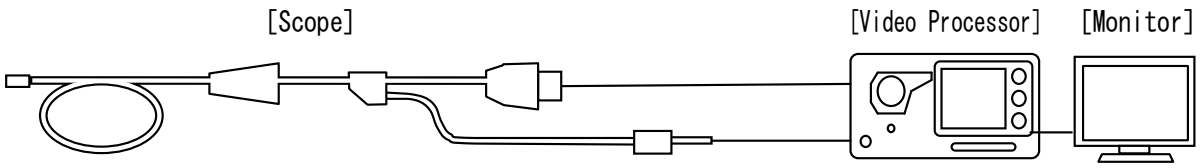
Trade/Device Name: Pentax Medical EKP-i5010 Video Processor with EB Family
The PENTAX Medical EPK-i5010 Video Processor (K143727) is the reference device for this submission.
This reference device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

PENTAX Medical ENT Video Imaging System consists of a PENTAX Medical Video Naso-Pharyngo-Laryngoscope (VNL-1570STK), PENTAX Medical Video Processor (EPK-i5010) and other ancillary equipment, which is intended for ENT endoscopic observation and diagnosis and naso-pharyngo-laryngoscope diagnosis and treatment.

The following two major sub-systems/devices with their required accessories and other ancillary equipment are part of this submission:

1. PENTAX Medical Video Naso-Pharyngo-Laryngoscopes (VNL-1570STK)
2. PENTAX Medical Video Processor (EPK-i5010)



PENTAX Medical Video Naso-Pharyngo-Laryngoscopes (VNL-1570STK):

The VNL-1570STK, Video Naso-pharyngo-laryngoscope is a reusable device initially supplied non-sterile to user and requiring the user to reprocess prior to initial use and between each use. According to the Spaulding classification scheme, the Video Naso-pharyngo-laryngoscopes are classified as semi-critical devices and are required to be thoroughly cleaned and then reprocessed by high level disinfection or sterilization, if sterilization is feasible. The Video Naso-pharyngo-laryngoscope is used with a compatible PENTAX Medical Video Processor and is intended to provide optical visualization (via a video monitor) of, and therapeutic access to, nasal, pharyngeal, laryngeal, and the upper airway anatomy.

The VNL-1570STK Video Naso-pharyngo-laryngoscope is composed of the following main parts: an Insertion Portion, Control Body, PVE Connector and Light Guide Plug.

The Insertion Portion is inserted into the body cavity of patient. The Insertion Portion includes the Distal End and Bending Section. The Objective Lens, Light Guide, and Instrument Channel Outlet are located on the Distal End of the Insertion Portion.

The Control Body is held in the user's hand. The Control Body includes the Angulation Control lever, Angulation Lock Lever, Suction Cylinder, Suction Nipple, Remote Button, and Instrument Channel Inlet. The Suction Control Valve is attached to the Suction Cylinder. The

Inlet Seal is attached to the Instrument Channel Inlet. The Bending Section is bent by the Angulation Control lever to operate the endoscope angulation. The Angulation Lock Lever is used to adjust the rotation torque of the Angulation Control Lever. The Suction Control System is used to suction the fluid and air in body cavity from the Instrument Channel. When the Suction Control Valve is pushed, the fluid and air are suctioned. The Remote Button is used to operate the function of video processor and external device from the control body, as necessary. Endoscopic accessories such as Biopsy Forceps are inserted from the Instrument Channel Inlet into the body cavity through the instrument channel.

The PVE Connector and the Light Guide Plug are separated from each other to enable the user to connect the PVE Connector with Video Processor via an Electrical Contact and the Light Guide Plug with compatible light source, such as video processor with built-in light source or other strobe light source. The Light Guide of the Distal End is used to illuminate the body cavity by light which is carried through the Light Carrying Bundle. The Light Carrying Bundle guides the light from Light Guide Plug which is connected to the Light Source. The CCD built into the Distal End receives reflected light (image data) from the body cavity, and sends the image data to the Video Processor through the video cable. The image data are converted into the image signal by the Video Processor, and the image inside the body cavity is displayed on the Monitor.

PENTAX Medical Video Processor (EPK-i5010):

The PENTAX Medical EPK-i5010 video processor consists of a video system, integrated light source, monitor, and ancillary equipment. This processor, when connected to a compatible ENT scope is intended for ENT endoscopic diagnosis, treatment and video observation.

The PENTAX Medical EPK-i5010 includes PENTAX i-Scan™, a digital, filter-based post-processing imaging enhancement technology with three modes, i-Scan 1, 2 and 3. i-Scan 1 enhances image topography and edges and i-Scan 2 and 3 enhance the color tone of the image by dissecting and recombining the individual red, green and blue (RGB) components of a white light image. The EPK-i5010 with i-Scan has been previously cleared for use with bronchoscopes, gastroscopes, colonoscopes, and duodenoscopes.

PENTAX i-Scan™ modes 1, 2, and 3, are intended to give the user an enhanced view of the texture of the mucosal surface and blood vessels. i-Scan 1 provides the user with a view that sharpens surface vessels and enhances surface texture of the mucosa. i-Scan 2 provides the user with increased visibility of blood vessels while also providing the same enhancements to the mucosa achieved in i-Scan 1. i-Scan 3 provides the user with increased visibility of blood vessels including dimly illuminated far-field regions while also providing the same enhancement to the mucosa achieved in i-Scan 1. The user can select either white light image or i-Scan modes by pressing a pre-programmed button on the scope, by using a pre-programmed foot pedal or by pressing a keyboard button. i-Scan is intended to be used as an optional adjunct following traditional white light endoscopy and is not intended to replace histopathological sampling.

White light is captured from a 300 Watt xenon lamp housed in the EPK-i5010 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. The modification of the combination of RGB components for each pixel occurs when the i-Scan function is turned on in the EPK-i5010 video processor. The resulting i-Scan image is then displayed on the observation monitor.

V. INDICATIONS FOR USE

PENTAX Medical ENT Video Imaging System consists of PENTAX Medical Video Naso-Pharyngo-Laryngoscope, PENTAX Medical Video Processor and other ancillary equipment.

1. PENTAX Medical Video Naso-Pharyngo-Laryngoscope

The PENTAX Medical Video Naso-Pharyngo-Laryngoscopes (VNL-1570STK) is designed to be used with a PENTAX Medical video processor, light source, documentation equipment, display monitor, endoscopic accessories, and other ancillary equipment and intended to provide optical visualization (via a video monitor) of, and therapeutic access to, nasal, pharyngeal, laryngeal and the upper airway anatomy.

2. PENTAX Medical Video Processor

The PENTAX Medical Video Processor (EPK-i5010) is intended to be used with the PENTAX Medical camera heads, compatible endoscopes, light sources, monitors and other ancillary equipment for ENT endoscopic observation and diagnosis, and naso-pharyngo-laryngoscopic diagnosis, and treatment.

The PENTAX Medical EPK-i5010 includes PENTAX i-Scan™, a digital, post-processing imaging enhancement technology.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The PENTAX Medical ENT Video Imaging System (subject device) has virtually the same intended use, indications for use, and fundamental operating principle as the OLYMPUS EVIS EXERA II Video System (K061313 -primary predicate device), with the exception that the subject device system is limited to ENT usage. Both devices are for use in ENT endoscopic observation, diagnosis and treatment in the nasal, pharyngeal, laryngeal and the upper airway anatomy. The devices differ slightly with regard to design and technological characteristics. Performance data, specifically optical bench testing and animal image comparison, are provided to support the determination of substantial equivalence of the devices.

The PENTAX Medical EPK-i5010 Video Processor used in this system level submission has the same intended use, design, fundamental operating principle, and scientific technology, including the PENTAX i-Scan image enhancement technology, compared to the commercially available PENTAX EPK-i5010 Video Processor (K143727 - reference device). The only substantive difference between the subject and reference device is in use of the device in different anatomical locations. The subject device is used for ENT observation, diagnosis, and treatment in the nasal, pharyngeal, laryngeal and the upper airway anatomy and the reference device is used for bronchoscopic diagnosis, treatment and observation in the pulmonary anatomical location.

VII. PERFORMANCE DATA

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

Biocompatibility Testing

Biocompatibility of direct and indirect contact materials were confirmed by testing the Cytotoxicity, Sensitization and Intracutaneous Reactivity of the materials of the of the VNL-1570STK with limited (less than 24 hours) contact with mucosal membrane in accordance with the ISO 10993-1, 5, and 10 Biological Evaluation of Medical Devices.

Reprocessing Validation, Sterilization and Shelf Life

Reprocessing Validation

Simulated use testing, soil accumulation analysis, cleaning, and high level disinfection validation studies of the VNL-1570STK and its accessories were conducted and confirmed the effectiveness of reprocessing procedures.

Sterilization and Shelf Life

PENTAX Medical coordinated with STERIS Corporation to validate the use of System 1E liquid chemical sterilization for the sterilization of the VNL-1570STK Video Naso-Pharyngo-Laryngoscope. The device is not provided sterile, therefore, shelf-life is not applicable.

Electrical Safety and electromagnetic compatibility (EMC)

The acceptable level of Electromagnetic Compatibility (EMC) and Electrical Safety (ES) for the PENTAX Medical ENT Video Imaging System has been confirmed by testing the VNL-1570STK and EPK-i5010 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 with the VNL-1570STK and EPK-i5010 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)

Bench Testing

Optical testing was performed to compare the PENTAX Medical ENT Video Imaging System with the predicate devices. Testing consisted of Signal to Noise**,** Color (IEE)**,** Resolution**,** Distortion**,** Light distribution**,** Spectral distribution, and Total luminous flux. It was concluded that the performance of the subject and predicate devices are equivalent.

Animal Study

In addition to Optical bench testing, a live porcine study was conducted to show the similarity of visual experience of the PENTAX Medical ENT Video Imaging System in comparison to the predicate system. The images captured during the study demonstrate no difference between systems in all of their enhancement settings.

VIII. CONCLUSIONS

After analyzing the intended use, indications for use, technological characteristics (including fundamental operating principle, energy source, scientific technology, functional characteristics, design features, and performance characteristics), labeling, and sterilization method, we conclude that the subject device, the PENTAX Medical ENT Video Imaging System, is substantially equivalent to the predicate, OLYMPUS EVIS EXERA II Video System. While there are some differences in technological characteristics, the PENTAX Medical ENT Video Imaging System is as safe and effective as the predicate device and none of the differences raise new questions of safety or effectiveness.