July 18, 2018

Pentax Medical
William Goeller
Vice President, Quality/Regulatory Affairs
3 Paragon Drive
Montvale, NJ 07645

Re: K171011
Trade/Device Name: PENTAX Medical VIVIDEO ENT Videoscope Solution
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: June 15, 2018
Received: June 18, 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171011

Device Name
PENTAX Medical VIVIDEO ENT Videoscope Solution

Indications for Use *(Describe)*
The PENTAX Medical VIVIDEO ENT Videoscope Solution includes the VIDEO NASO-PHARYNGO-LARYNGOSCOPE VNL9-CP and VIVIDEO VIDEO PROCESSOR CP-1000. It is intended to be used with a medical video monitor for endoscopic examination between the upper respiratory tracts of the nasal passage and the vocal cords. This PENTAX Medical VIVIDEO ENT Videoscope Solution must only be used in a clinical or ambulatory medical environment.

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

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.

Applicant: PENTAX Medical
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Date Prepared: 6/8/2018

Common Name: Nasopharyngoscope (Flexible or Rigid)
Trade Name: PENTAX Medical VIVIDEO ENT Videoscope Solution
Regulation Number: 21 CFR Part 874.4760
Regulation Name: Nasopharyngoscope and accessories
Regulatory Class: Class II
Product Code: EOB
Predicate Device: KARL STORZ CMOS Flexible Video Rhino-Laryngoscope System (K103467, clearance received on June 28, 2012)

Device Description:
The PENTAX Medical VIVIDEO ENT Videoscope Solution includes the video processor CP-1000 and the video naso-pharyngo-laryngoscope VNL9-CP. The naso-pharyngo-laryngoscope consists of a handheld device with a flexible thin insertion tube. The illuminating LED is integrated in the handle while light is transmitted to the distal end through a bundle of fiber optic cables within the insertion tube. A CMOS video sensor is located at the bendable distal tip. The video signal of the sensor is transferred to the CP-1000 Video Processor for displaying the video image together with other information on an attached monitor and for recording video sequences or still images to a USB storage device.

Intended Use/Indications for Use:
The PENTAX Medical VIVIDEO ENT Videoscope Solution includes the VIDEO NASO-PHARYNGOLARYNGOSCOPE VNL9-CP and VIVIDEO VIDEO PROCESSOR CP-1000. It is intended to be used with a medical video monitor for endoscopic examination between the upper respiratory tracts of the nasal passage and the vocal cords. This PENTAX Medical VIVIDEO ENT Videoscope Solution must only be used in clinical or ambulatory medical environment.

The device may only be used by persons with an appropriate medical qualification who have thoroughly studied all the characteristics of this device and who are acquainted with the endoscopic technique.

Summary of Technology Characteristics:
The PENTAX Medical VIVIDEO ENT Videoscope Solution is functionally equivalent to its predicate device, the KARL STORZ CMOS Flexible Video Rhino-Laryngoscope System. The only difference between the two devices is that the predicate contains a combined monitor and video processor, whereas the subject device contains a separate monitor and video processor.

While there are some differences in the dimensional specifications in the subject device, these differences have 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.

	Subject Device	**Predicate Device**
Applicant	PENTAX Medical	KARL STORZ
Device Name	VIVIDEO ENT Videoscope Solution	CMOS Flexible Video Rhino-Laryngoscope System (K103467)
Type of Device	Videoscope System	Videoscope System
Indications for use	For endoscopic examination between upper respiratory tracts of the nasal passage and the vocal cords.	For endoscopic diagnosis within the nasal lumens and airway anatomy
Working Length	Same	Same
Shaft Diameter	3.6mm	3.7mm
Integrated CMOS sensor	Same	Same
Scope-integrated LED illumination	Same	Same
No internal channels	Same	Same
Data Storage Capability	Yes	Yes

Non-Clinical Performance Data
The PENTAX Medical VIVIDEO ENT Videoscope Solution has been successfully tested for its functions, performance and safety as per FDA recognized consensus standards. Testing has been conducted as per IEC60601-1, IEC 60601-1-2, IEC 62471, and ISO 10993. The following performance data are provided in support of the substantial equivalence determination.

Optical Testing
Optical properties including signal to noise ratio, spatial resolution (MTF), distortion, light distribution, and spectral distribution were measured for the video naso-pharyngo-laryngoscope VNL9-CP in conjunction with the CP-1000 video processor. All results show that there are no differences between the subject device, PENTAX Medical VIVIDEO ENT Videoscope Solution, and the predicate device, KARL STORZ CMOS Flexible Video Rhino-Laryngoscope System.

Reprocessing Validation
Simulated use testing, cleaning, high level disinfection, and rinsing (after cleaning and after HLD) validation studies of the VIVIDEO ENT Videoscope Solution and its accessories were conducted and confirmed the effectiveness of reprocessing procedures in accordance with FDA's 2015 Final Guidance, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling ("FDA's 2015 Reprocessing Guidance"). Acceptance criteria were established in accordance with AAMI TIR 30:2011 for amount of residual soil accumulation and extraction efficiency. Acceptance criteria were met after each phase of reprocessing.

Sterilization and Shelf Life
PENTAX Medical coordinated with STERIS Corporation to validate the use of System 1E liquid chemical sterilization for sterilization of the VIVIDEO ENT Videoscope Solution. The device is not provided sterile, therefore, shelf-life is not applicable.

Biocompatibility
Biocompatibility of direct and indirect contact materials was confirmed by assessing the cytotoxicity, sensitization, and intracutaneous reactivity of the surface device with limited (less than 24 hours) contact with mucosal membrane in accordance with ISO 10993-1, 5, and 10: Biological Evaluation of Medical Devices.

A biocompatibility assessment of the amount of carbon black and titanium oxide contained in the patient contact parts of the device as well as the tolerable exposure (TE) value was conducted. The risk level of colorant was determined as "Very Low" based on the low concern for toxicity of colorant. The risk level of local toxicity was determined as "Acceptable" as a result of the biocompatibility testing.

Software
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 A 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."

Cybersecurity risks have been assessed and mitigated according to the FDA Guidance for Industry and Staff "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices."

EMC and Electrical Safety
The acceptable level of electromagnetic compatibility (EMC) and electrical safety (ES) for the PENTAX VIVIDEO ENT Videoscope Solution were confirmed by the following standards:
IEC 60601-1-2:2001, A1:2004; IEC 60601 1:2005+CORR 1:2006+CORR 2:2007+AM 1:2012; and IEC 60601-2-18:2009.

Substantial Equivalence Discussion:
After analyzing the intended use, indications for use, technological characteristics (including fundamental operating principle, energy source, scientific technology, functional characteristics, design features, performance characteristics, and constituent materials), labeling, and sterilization method, we conclude that the subject device PENTAX Medical VIVIDEO ENT Videoscope Solution is as safe and effective as the predicate device, KARL STORZ CMOS Flexible Video Rhino-Laryngoscope System. The differences in indications for use and intended use between the subject and predicate device do not raise new concerns of safety and effectiveness and are therefore, substantially equivalent. The technological differences in terms of design features, performance characteristics and constituent materials are not substantive.

Conclusion:
Accordingly, PENTAX Medical believes the PENTAX Medical VIVIDEO ENT Videoscope Solution is substantially equivalent to the identified predicate, KARL STORZ CMOS Flexible Video Rhino-Laryngoscope System, cleared by FDA in 2009.