November 16, 2022

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

Re: K220465
Trade/Device Name: PENTAX Medical EPK-3000 Video Imaging System
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, PEA, EQL, OUG
Dated: October 14, 2022
Received: October 17, 2022

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220465

Device Name
PENTAX Medical EPK-3000 Video Imaging System

Indications for Use *(Describe)*
PENTAX Medical EPK-3000 Video Processor is intended to be used with the PENTAX Medical camera heads with PENTAX sinuscopes (8890, 8891, 8892, 8893), PENTAX Medical VNL8-J10, VNL11-J10, and VNL15-J10 endoscopes, PENTAX Medical Laryngeal Strobe, video monitors and other ancillary equipment for ENT endoscopic observation and 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220465

Device Name
PENTAX Medical ENT Video Imaging System

Indications for Use *(Describe)*
The PENTAX Medical Video Processor (EPK-i5010) is intended to be used with the PENTAX Medical camera heads with PENTAX sinuscopes (8890, 8891, 8892, 8893), PENTAX Medical VNL-1570STK, VNL8-J10, VNL11- J10, and VNL15-J10 endoscopes, PENTAX Medical Laryngeal Strobe, video monitors and other ancillary equipment for ENT endoscopic observation and ENT diagnosis, treatment and video observation with or without stroboscopy.

The PENTAX Medical EPK-i5010 Video Processor 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)

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5. 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.

1 SUBMITTER

Applicant: PENTAX Medical
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Vice President, Quality and Regulatory Affairs
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Date Prepared: 02/08/2022

2 SUBJECT DEVICE

PENTAX Medical is seeking clearance of two Imaging Systems that include a new camera head product, the PENTAX Medical Camera Head PVK-J10.
This product is used in conjunction with 3rd party non-video endoscopes (such as a rigid scope) and converts light captured by the non-video scope into video images through a processor, to be displayed on a monitor. Addition of the camera head expands utility of the video imaging systems by providing compatibility with additional ENT scopes.

PENTAX Medical Camera Head PVK-J10 is compatible with following two systems:

- PENTAX Medical EPK-3000 Video Imaging System
- PENTAX Medical ENT Video Imaging System

Compatible Endoscopes for above systems are as follows;

- Video Endoscopes : VNL-1570STK, VNL15-J10, VNL11-J10, VNL8-J10
- Add-on Camera Head: PENTAX Medical camera head PVK-J10 with previously cleared Sinuscope models 8890, 8891,8892, 8893.

The regulatory classification of PENTAX Medical Camera Head PVK-J10 is identified in Table 5.1.

Table 5.1: Regulatory Classification of PENTAX Medical Imaging Systems with PVK-J10 Camera Head

Device Names	PENTAX Medical EPK-3000 Video Imaging System
Common Name	Naso-Pharyngo-Laryngoscope
Classification Name	Nasopharyngoscope (Flexible or Rigid) and Accessories
Regulation No.	874.4760
Device Class	II
Product Code	EOB, PEA, EQL, OUG
Classification Panel	Ear Nose & Throat

Device Names	PENTAX Medical ENT Video Imaging System
Common Name	Naso-Pharyngo-Laryngoscope
Classification Name	Nasopharyngoscope (Flexible or Rigid) and Accessories
Regulation No.	874.4760
Device Class	II
Product Code	EOB, PEA, EQL, OUG
Classification Panel	Ear Nose & Throat

3 PREDICATE DEVICE

The Predicate Devices for each Subject Devices are identified in Table 5.2.
And Figure 5.1 shows system difference between Predicate Devices and Subject Devices

Table 5.2: Subject Device and Predicate Device relation

Subject Device	Predicate Device	Predicate Device 510(k) Clearance Number
PENTAX Medical EPK-3000 Video Imaging System	PENTAX Medical EPK-3000 Video Imaging System	K172156, K182846
PENTAX Medical ENT Video Imaging System	PENTAX Medical ENT Video Imaging System	K183691

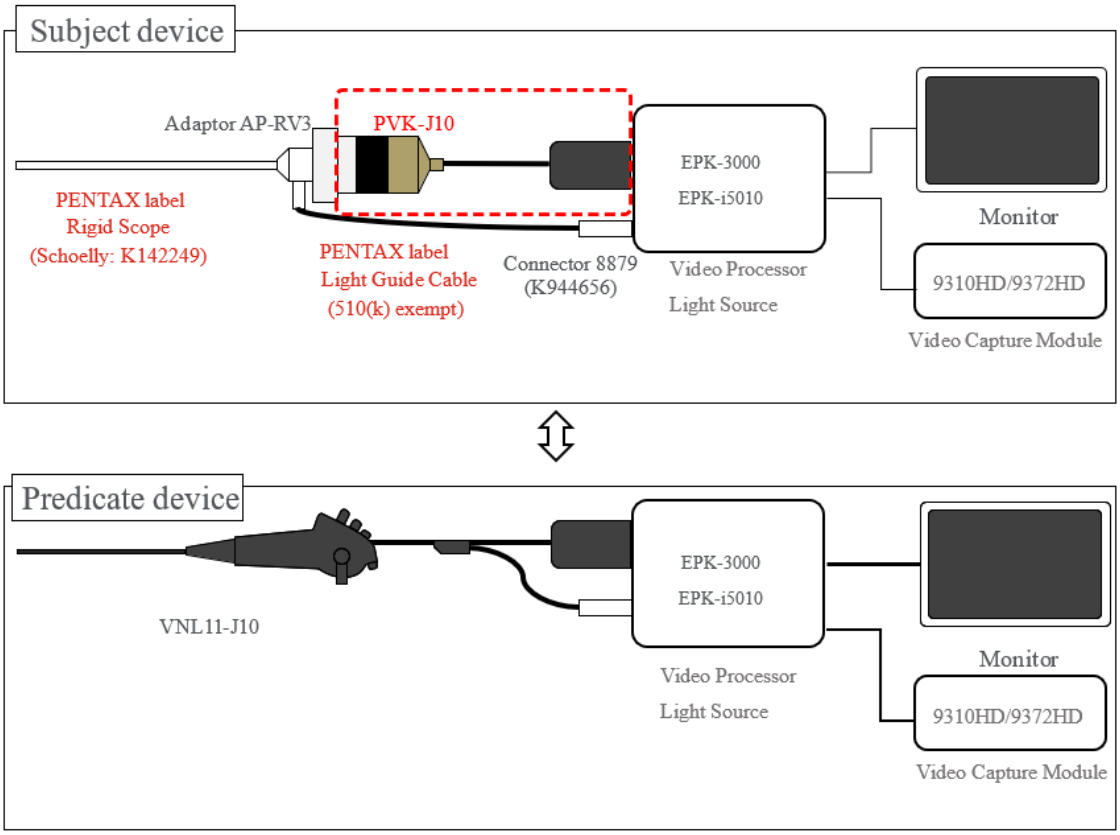

Figure 5.1. System configuration difference Predicate Devices and Subject Devices

4 DEVICE DESCRIPTION

PENTAX Medical EPK-3000 and ENT Video Imaging Systems are 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 new component to be added to the subject system is the PENTAX Medical Camera Head, model PVK-J10. The PVK-J10 is used in conjunction with a non-video endoscope, video processor, and light guide. The non-video endoscope is connected to the video processor via the camera head and the light guide. The light supplied from the video processor is transmitted to the distal end of the endoscope via the light guide and connector in order to illuminate the patient's body cavity. Light captured by the endoscope are converted into the video signals by the camera head, and the signals are transferred to the video processor to display the video images on the monitor.

The PVK-J10 camera head connects to rigid, non-video sinuscopes (K142249). It takes images formed on the ocular lens by CCD sensor inside the control head, and transmits the image signal to the video processor. Image signal from CCD sensor is adjusted in terms of color, contrast, etc.,

inside the video processor, and displayed on video equipment such as a monitor.

The camera head has a zoom function with focal lengths of 6.5 mm for the wide end and 13mm for the telephoto end.

The video processors to be connected to the PVK-J10 camera head and light guides are PENTAX Medical Video Processors EPK-i5010 and EPK-3000, both of which have been cleared.

PENTAX Medical sinuscopes 8890, 8891,8892, 8893, manufactured by Schoelly Fiberoptic GmbH and cleared under K142249. The light guides 8899HT and 8898HT used to connect PVK-J10 with these endoscopes are also manufactured by Schoelly Fiberoptic GmbH. PENTAX Medical sell Schoelly Sinuscopes and light guide as private brand, Model Name combination are shown in Table 5.3

Table 5.3:PENTAX Private Brand Name and Schoelly Item Number Combination

Sinuscopes		Light Guides		K# Schoelly
PENTAX Medical Model Number	Schoelly Item number	PENTAX Medical Model Number	Schoelly Item number	
8893	31.0801a	8899HT	05.0090I.ht	K142249
8890	31.0804a			
8892	31.0810a	8898HT	05.0088I.ht	
8891	31.0811a			

5 INTENDED USE AND INDICATIONS FOR USE

PENTAX Medical EPK-3000 Video Imaging System
PENTAX Medical EPK-3000 Video Processor is intended to be used with the PENTAX Medical camera heads with PENTAX sinuscopes (8890, 8891, 8892, 8893), PENTAX Medical VNL8-J10, VNL11-J10, and VNL15-J10 endoscopes, PENTAX Medical Laryngeal Strobe, video monitors and other ancillary equipment for ENT endoscopic observation and 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.

PENTAX Medical ENT Video Imaging System
The PENTAX Medical Video Processor (EPK-i5010) is intended to be used with the PENTAX Medical camera heads with PENTAX sinuscopes (8890, 8891, 8892, 8893),

PENTAX Medical VNL-1570STK, VNL8-J10, VNL11- J10, and VNL15-J10 endoscopes, PENTAX Medical Laryngeal Strobe, video monitors and other ancillary equipment for ENT endoscopic observation and ENT diagnosis, treatment and video observation with or without stroboscopy.

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

6 COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE

The subject Imaging systems that include the PENTAX Medical PVK-J10 Camera Head are functionally equivalent to the predicate devices, PENTAX Medical EPK-3000 Video Imaging (K172156, K182846) and PENTAX Medical ENT Video Imaging System (K183691) . The main difference between the subject and the predicate are minor technological changes that add a compatible Camera Head with sinuscope to the predicate systems.

The changes in the subject device 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 devices.

The optical components of the PENTAX Medical Camera Head have the same fundamental technology (Software, Type of Image Sensor, CCD Pixel) as the optical components of the predicate device. Both the PENTAX Medical Camera Head and the predicate device are intended for illuminating and viewing the inside of the human body. Subject devices that add PVK-J10 with sinuscope to the predicate system configurations have the same visual capabilities as the predicate systems. This has been successfully substantiated by a series of bench tests and the clinical image capture study.

Both subject and the predicate scopes are reprocessed by the user.

7 NON-CLINICAL PERFORMANCE DATA

The PENTAX Medical Imaging Systems with PVK-J10 Camera Head have been successfully tested for their function, performance and safety as per FDA recognized consensus standards. The following performance data are provided in support of the substantial equivalence determination.

Operational and Reprocessing Instructions for Use are provided for the PVK-J10.

i. *Reprocessing Validation*
As result of the assessment, simulated use testing, cleaning, high level disinfecting and rinsing (after cleaning and after HLD) validation studies of PVK-J10 was 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.
All acceptance criteria were satisfied.

ii. *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 PVK-J10. The device is not provided sterile, therefore, shelf-life is not applicable.

iii. *Biocompatibility*
PVK-J10 is the camera head used in combination with scope and non-contact with patients, therefore biocompatibility evaluation is not applicable.

iv. *Software and Cybersecurity*
Software verification and validation including cybersecurity assessments were conducted according to IEC 62304: 2006 and FDA Guidances for Industory and Staff "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.*", "*Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*" and "*Postmarket Management of Cybersecurity in Medical Devices.*"

v. *Electrical Safety and EMC*
The acceptable level of electrical safety (ES) and electromagnetic compatibility (EMC) for the PENTAX Medical Camera Head PVK-J10 was confirmed by the following standards: IEC 60601-1-2:2014; IEC 60601-1:2005+CORR 1:2006+CORR 2:2007+A1:2012; and IEC 60601-2-18:2009.

vi. *System Performance*
The system performance of the subject devices demonstrated the equivalence to the predicate devices. Test results also demonstrated six years of the service life for the PVK-J10 and AP-RV3 (PENTAX Medical Endoscope Mount Adapter for Rigid Ocular Endoscopes)

vii. *Optical Performance*
As a part of Design Verification and Validation, optical properties of imaging and illumination performances were measured for the PVK-J10 with representative Sinuscopes and light guides in conjunction with the EPK-3000 and EPK-i5010 Video Processors. All results show that the optical characteristics of the subject device is equivalent to those of the predicate device.

viii. *Photobiological Safety of lamps and lamp systems*

PENTAX Medical evaluated the photobiological safety of lamps and lamp systems for the PVK-J10 with the representative Sinuscope and light guide in conjunction with the EPK-3000 and EPK-i5010 Video Processors. The results show that all hazards related to the photobiological safety are acceptable for the subject device.

ix. *Animal Image Capture Study*

N/A

x. *Clinical Image Capture Study*

Clinical image capture study was performed as a part of optical and color performance testing. In this study, the Imaging systems with PVK-J10 and Sinuscope 8893 and PVK-J10 with Sinuscope 8891 were used as the representative model. The results indicate that the subject device is able to visualize structure, vascularity and mucosal surface as well or better than the predicate device.

8 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, PENTAX Medical concludes that the subject Imaging Systems with PVK-J10 camera head are as safe and effective as the predicate devices. There are no differences in indications for use and intended use between the subject and predicate devices The technological differences in terms of design features, performance characteristics and constituent materials are not substantive. Thus, the subject and predicate devices are substantially equivalent.

9 CONCLUSION

Accordingly, PENTAX Medical believes the PENTAX Medical Imaging systems with PVK-J10 Camera Head are substantially equivalent to the identified predicates, PENTAX Medical EPK-3000 video imaging system (K172156 and K182846) and PENTAX Medical ENT Video Imaging System (K183691).