December 2, 2022

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

Re: K223072
Trade/Device Name: PENTAX Medical Video Esophagoscope EE17-J10
Regulation Number: 21 CFR 874.4710
Regulation Name: Esophagoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOX
Dated: September 28, 2022
Received: September 30, 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)*
K223072

Device Name
PENTAX Medical Video Esophagoscope EE17-J10

Indications for Use *(Describe)*
The PENTAX Medical Video Esophagoscope EE17-J10 is intended to provide optical visualization of (via a video monitor), and therapeutic access to, the upper gastrointestinal tract. This anatomy includes the organs, tissues, and subsystems of esophagus and gastro-esophageal junction.
This endoscope is introduced via the mouth or nose when indications consistent with the need for the procedure are observed in adult and pediatric patient populations.

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

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

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Date Prepared: 09/28/2022

2 SUBJECT DEVICE

PENTAX Medical is seeking clearance of a new product of PENTAX Medical Video Esophagoscope EE17-J10 with the compatible PENTAX Medical Video Processors EPK-i7010 and EPK-3000.

Table 5.1: Regulatory Classification of PENTAX Medical Video Esophagoscope EE17-J10

Device Names	PENTAX Medical Video Esophagoscope EE17-J10
Common Name	Esophagoscope
Classification Name	Esophagoscope (Flexible Or Rigid)
Regulation No.	874.4710
Device Class	II
Product Code	EOX
Classification Panel	Ear Nose & Throat

3 PREDICATE DEVICE

The predicate device for this submission is Karl Storz Trans-Nasal Esophagoscope models 11301BN1and 11302BD1 (K051972).

Both subject device and predicate device are used for variety of diagnostic and

therapeutic procedures in the esophagus and gastro-esophageal junction, however the predicate models (11301BN1and 11302BD1) cover additional ENT areas like nasal sinuses and larynx.
As to the design differences, The Karl Storz Trans-Nasal Esophagoscopes are manually operated surgical devices, that utilize fiber-optic technology. Whereas EE17-J10 utilizes the latest HD quality white light imaging combined with two forms of image enhancement technologies: i-SCAN and OE. To compare old fiber optic technology to the latest HD quality is not appropriate due to the modern technological advancements in the latter category that lead to superior image quality. Instead, PENTAX Medical will be using a cleared reference device EG17-J10 (K210177) with similar technology for performance characteristics comparison and substantial equivalence establishment between EE17-J10 and EG17-J10.

4 DEVICE DESCRIPTION

PENTAX Medical Video Esophagoscope EE17-J10
The PENTAX Medical Video Esophagoscope EE17-J10 is intended to be used with a PENTAX Video Processor, video monitor, endoscopic device and other ancillary equipment for optical visualization (via a video monitor) of, and/or therapeutic access to the esophagus and Gastro-Esophageal Junction. This anatomy includes, the following organs, tissues; and subsystems: Esophagus and Gastro-Esophageal Junction.

The EE17-J10 is composed of the following main parts: an insertion portion, control body and PVE connector. 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, instrument channel and air/water nozzle are located on the distal end of the insertion portion. The control body is held by the user's hand. The control body includes the angulation control knob, angulation lock knob/lever, air/water cylinder, suction cylinder, remote button, and instrument channel inlet. The air/water feeding valve is attached to the air/water cylinder, and the suction control valve is attached to the suction cylinder. The inlet seal is attached to the instrument channel inlet. The PVE connector is connected to the video processor via electrical contacts.

The bending section is bent by the angulation control knob to operate the endoscope angulation. The angulation lock knob/lever is used to adjust the rotation torque of the angulation control knob.

The air/water feeding system is used to deliver the air and water to the objective lens from the air/water nozzle. When the hole at the top of air/water feeding valve is covered, the air is delivered. When the air/water feeding valve is pushed, the water is delivered. 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 functions of the video processor and any external device from the control body, as necessary.

Endoscopic devices such as biopsy forceps are inserted from the instrument channel Inlet into the body cavity through the instrument channel.

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 inside the Video Processor. 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.

The PENTAX Medical Video Processors EPK-i7010 and EPK-3000 are compatible with PENTAX Medical Video Esophagoscope EE17-J10.

The PENTAX Medical Video Esophagoscope EE17-J10 is provided with the following accessories:

- Inlet Seal - prevents suctioned fluid from coming out of the instrument Channel Inlet during the use of suction function. During reprocessing, it seals the instrument Channel Inlet in order to fill 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.
- Air/Water Valve - intended to control air and water feeding.

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

5 INTENDED USE AND INDICATIONS FOR USE

Intended use and Indications for use for PENTAX Medical Video Upper GI Scope EE17-J10
The PENTAX Medical Video Esophagoscope EE17-J10 is intended to provide optical visualization of (via a video monitor), and therapeutic access to, the upper gastrointestinal tract. This anatomy includes the organs, tissues, and subsystems of esophagus and gastro-esophageal junction.
This endoscope is introduced via the mouth or nose when indications consistent with the need for the procedure are observed in adult and pediatric patient populations.

6 COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE

The PENTAX Medical Video Esophagoscope EE17-J10 is functionally equivalent to the predicate device, the Karl Storz Trans-Nasal Esophagoscope models 11301BN1and 11302BD1 (K051972). The Intended Uses of the predicate and subject devices are very similar, as they both are used to perform endoscopic procedures in the esophagus and gastro-esophageal junction. Both EE17-J10 and the predicate Karl Storz Trans-Nasal

Esophagoscopes are intended for illuminating and viewing the inside of the human body. The patient contacting components of both the subject and predicate devices are biocompatible. Both subject and the predicate scopes are reprocessed by the user.
The changes in the subject device 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.

Since the predicate and subject devices utilize different technologies, the substantial equivalence will be evaluated through performance testing and comparison to the reference device PENTAX Medical Video Upper GI Scope EG17-J10 (K210177) which share the same design as EE17-J10.

The components of the PENTAX Medical Video Esophagoscope EE17-J10 have the same fundamental technology and operating principles as the reference device (EG17-J10). The components of the PENTAX Medical Video Esophagoscope EE17-J10 consist of the same components as the reference device (EG17-J10), including:

- A video processor
- Video Upper GI Scopes to provide optical visualization of (via a video monitor), and therapeutic access to the Upper Gastrointestinal Tract.
- Accessories, including but not limited to a keyboard, foot switch, White Balance Adjuster, and Condenser Earth Cable

The only design difference between subject and reference devices is in the Scope working length (has a shorter working length for EE17-J10). Therefore, the subject device is identical or enhanced to the reference device with regard to

- Direction of view
- Field of view
- Depth of field
- Tip angulation
- Rigid distal width
- Insertion tube width
- Maximum insertion portion width
- Maximum instrument channel width
- Software
- Materials

7 NON-CLINICAL PERFORMANCE DATA

The PENTAX Medical Video Esophagoscope EE17-J10 has been successfully tested for their functions, 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 scope.

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 EE17-J10 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.
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 EE17-J10 The device is not provided sterile, therefore, shelf-life is not applicable.

iii. *Biocompatibility*
Biocompatibility of the EE17-J10 scope on direct and indirect contact materials was confirmed by assessing the cytotoxicity, sensitization, and intracutaneous reactivity. The risk levels of local toxicity were determined as "Acceptable" as a result of applying the risk level of local toxicity to the risk evaluation criteria.

iv. *Software and Cybersecurity*
Software verification and validation including cybersecurity assessments were conducted according to IEC 62304: 2006 + A1: 2015 and FDA Guidances for Industry 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 Video Esophagoscope EE17-J10 were 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 device demonstrated the equivalence to the reference device. Test results also demonstrated six years of the service life for the EE17-J10.

vii. *Optical Performance*
As a part of Design Verification and Validation, optical properties of imaging and illumination performances were measured for the PENTAX Medical Video Esophagoscope EE17-J10 in conjunction with the EPK-i7010, and EPK-3000 Video Processors. All results

show that the optical characteristic of the subject device is equivalent to those of the reference device.

viii. *Clinical Image Capture Study*

A clinical image capture study was performed to demonstrate the maneuverability of the EE17-J10 endoscope and its ability to capture images at each of the pre-determined anatomical areas when used in a clinical setting.

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 device PENTAX Medical Video Esophagoscope EE17-J10 is as safe and effective as the predicate device. The Intended Uses of the subject and predicate devices are similar, except for nasal sinuses and larynx that are excluded from the subject device and are therefore, substantially equivalent. The technological differences in terms of design features, performance characteristics and constituent materials are not substantive.

8 CONCLUSION

Accordingly, PENTAX Medical believes the PENTAX Medical Video Esophagoscope EE17-J10 is substantially equivalent to the identified predicate, Karl Storz Trans-Nasal Esophagoscope models 11301BN1and 11302BD1 (K051972). Due to technological obsolesce of the predicate device, the design and technological characteristics of the subject EE17-J10 is compared to those of the reference device EG17-J10 (K210177). EE17-J10 and EG17-J10 are substantially equivalent in terms of endoscopic design, specifications and optical performance