January 19, 2018

PENTAX of America, Inc.
James W. Monroe, Director RA
PENTAX Medical
3 Paragon Drive
Montvale, NJ 07645-1782

Re: K173554
Trade/Device Name: PENTAX Medical Video Bronchoscopes, PENTAX Medical Video Naso-Pharyngo-Laryngoscope, and PENTAX Medical Ultrasound Video Bronchoscope
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ, EOB, ITX
Dated: November 10, 2017
Received: November 17, 2017

Dear James 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,

Srinivas Nandkumar -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173554

Device Name
PENTAX Medical Video Bronchoscopes (EB Family)

Indications for Use *(Describe)*
Device Name: PENTAX Medical Video Bronchoscopes (EB Family): The PENTAX Video Bronchoscopes (EB Family) have been designed to be used with a PENTAX Video Processor (including Light source), documentation equipment, video monitor, endo-therapy accessories (such as biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the airways and tracheobronchial tree.

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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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:

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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)*
K173554

Device Name
PENTAX Medical Video Naso-Pharyngo-Laryngoscope

Indications for Use *(Describe)*
The PENTAX Medical Video Naso-Pharyngo-Laryngoscope (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.

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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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)*
K173554

Device Name
PENTAX Medical Ultrasound Video Bronchoscope

Indications for Use *(Describe)*
Device Name: PENTAX Medical Ultrasound Video Bronchoscopes, EB-1970UK: The EB-1970UK, Ultrasound Video Bronchoscope, is intended to provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the Pulmonary Track including but not restricted to the organs, tissues, and subsystems: Nasal Passage, Pharynx, Trachea Tree (including access beyond the stem), and underlying areas. The instrument is introduced per orally when indications consistent with the requirement for 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)

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510(k) Summary

I. SUBMITTER

PENTAX of America, Inc.,
HOYA Corporation PENTAX Division
3 Paragon Drive
Montvale, New Jersey 07645-1782
Phone: 201-571-2318 Ext 2318
Fax: 201-571-2340

Contact: James W. Monroe
Date Prepared: December 5, 2017

II. DEVICE

The purpose of this 510(k) is to obtain clearance for the addition of epoxy to the suction nipple of the PENTAX Medical Video Bronchoscopes (EB Family), PENTAX Medical Video Naso-Pharyngo-Laryngoscope (VNL-1570STK) and PENTAX Medical Ultrasound Video Brochoscope (EB-1970UK) to prevent loosening of the suction nipple. There are no changes to the intended use or indications for use of the EB scopes, VNL-1570STK or EB-1970UK.

Table 5.1: Regulatory Classification of PENTAX Medical Video Bronchoscopes, Naso-Pharyngo-Laryngoscope, and Ultrasound Video Bronchoscope

Device Name	PENTAX Medical Video Bronchoscopes	PENTAX Medical Video Naso-Pharyngo-Laryngoscope	PENTAX Medical Ultrasound Video Bronchoscope
Common Name	Bronchoscope	Nasopharyngoscope	Bronchoscope
Classification Name	Bronchoscopes (flexible or rigid) and accessories	Nasopharyngoscope (flexible or rigid) and accessories	Bronchoscope (flexible or rigid) and accessories Diagnostic Ultrasound Transducer
Regulation No.	874.4680	874.4760	874.4680, 892.1570
Device Class	2	2	2
Product Code	EOQ	EOB	EOQ, ITX
Classification Panel	Ear, Nose, & Throat	Ear, Nose, & Throat	Radiology

III. PREDICATE DEVICES

The predicate devices for this submission are also the subject devices of this submission (see

Table 5.2). The predicate devices are identical to the devices subject to this 510(k) with the exception of the addition of epoxy to the suction nipple of the subject scopes.

Table 5.2: Subject vs. Predicate Devices

Subject Device	PENTAX Medical Video Bronchoscopes	PENTAX Medical Video Naso- Pharyngo-Laryngoscope	PENTAX Medical Ultrasound Video Bronchoscope
Predicate Device	PENTAX Medical Video Bronchoscopes	PENTAX Medical Video Naso- Pharyngo-Laryngoscope	PENTAX Medical Ultrasound Video Bronchoscope
Predicate Device	K131028	K162151	K081518

IV. DEVICE DESCRIPTION

The PENTAX Medical Video Bronchoscopes, Video Naso-Pharyngo-Laryngoscope and Ultrasound Video Bronchoscope are identical to their respective predicate devices with the sole exception being that epoxy has been added to the suction nipple of the subject devices to prevent loosening of the suction nipple. There are no other changes to the design, specifications, or technological characteristics of the predicate devices as described in K131028 (EB family), K162151 (VNL-1570STK) and K081518 (EB-1970UK).

The model numbers for the PENTAX Medical Video Bronchoscopes, Naso-Pharyngo-Laryngoscope and Ultrasound Video Bronchoscope that are applicable to this 510(k) are provided in Table 5.3.

Both the Bronchoscopes and Naso-Pharyngo-Laryngoscope are composed of an Insertion Portion, Control Body, PVE Connector and Light Guide Plug. In addition to the parts above, the Ultrasound Video Bronchoscope has an Ultrasound Umbilical Connector.

All the Bronchoscopes, Naso-Pharyngo-Laryngoscope and Ultrasound Video Bronchoscope are reusable devices initially supplied non-sterile to the user and require the user to reprocess prior to initial use and between each use. All the Bronchoscopes, Naso-Pharyngo-Laryngoscope and Ultrasound Video Bronchoscope are used with compatible PENTAX Medical Video Processors.

Table 5.3: EB and VNL Model Numbers associated with addition of epoxy to suction nipple

Scope Family	Model Number
EB Family	EB-1170K EB-1570K EB-1970K EB-1970TK
VNL Family	VNL-1570STK

Ultrasound Video Bronchoscope	EB-1970UK

V. INDICATIONS FOR USE

There are no changes to the Indications for Use for the subject devices. The sole purpose of this 510(k) is to obtain clearance for the addition of epoxy to the suction nipple of the scopes.

The PENTAX Medical Video Bronchoscopes (EB Family) have been designed to be used with a PENTAX Medical Video Processor (including Light source), documentation equipment, video monitor, endo-therapy accessories (such as biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the airways and tracheobronchial tree.

The PENTAX Medical Video Naso-Pharyngo-Laryngoscope (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.

The EB-1970UK, Ultrasound Video Bronchoscope, is intended to provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the Pulmonary Track including but not restricted to the organs, tissues, and subsystems: Nasal Passage, Pharynx, Trachea, Bronchial Tree (including access beyond the stem), and underlying areas. The instrument is introduced per orally when indications consistent with the requirement for procedure are observed in adult and pediatric populations.

VI. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE

The subject devices are identical to the predicate devices with the exception of the addition of epoxy to prevent loosening of the suction nipple of the subject devices. The subject devices have the same fundamental technology and operating principles as the predicate device, including the same intended use and technological characteristics, such as Insertion Portion, Control Body and fiberoptics illumination. There are no differences in specifications, including, but not limited to, depth of field, distal end width, insertion tube width, instrument channel width, and total length. The sole difference between the subject and predicate devices is the addition of epoxy to the suction nipple of the scopes. This modification does not impact the intended use and does not raise different questions of safety and effectiveness.

VII. PERFORMANCE DATA

The addition of epoxy to the suction nipple of the EB, VNL and EB-1970UK scopes do not affect the biocompatibility, reprocessing, electrical safety, electromagnetic compatibility, or software

verification and validation.

Performance testing of the suction nipple sub-assembly under stress conditions utilizing epoxy materials was conducted to determine the force (torque) required to loosen the subassembly. The results indicate that the subject epoxy has adequate adhesive strength to prevent looseness of the suction nipple under all stress conditions specified by the protocol.

VIII. CONCLUSION

The subject and predicate devices are identical with the exception of the addition of epoxy to the suction nipple. The subject devices have the same intended use and technological characteristics as the predicate devices. There are no other changes to the design of the subject devices.

The performance data indicates that the subject devices with epoxy applied to the suction nipple have adequate adhesive strength to prevent looseness of the suction nipple under stress conditions. The data provided in this 510(k) Premarket Notification support the equivalence of the subject and predicate devices.