December 30, 2020

PENTAX of America, Inc.
% Fumiaki Kanai
President & CEO
MIC International
4-1-17 Hongo
Bunkyo-ku, Tokyo 113-0033
JAPAN

Re: K203166
Trade/Device Name: PENTAX Medical Ultrasound Upper GI Video Scope EG34-J10U
PENTAX Medical Ultrasound Upper GI Video Scope EG36-J10UR
PENTAX Medical Ultrasound Upper GI Video Scope EG38-J10UT
PENTAX Medical Ultrasound Video Bronchoscope EB19-J10U
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODG, ITX, EOQ
Dated: December 1, 2020
Received: December 4, 2020

Dear Fumiaki Kanai:

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,

for
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203166

Device Name
PENTAX Medical EG-J10U Endoscopic Ultrasound System - EG34-J10U Ultrasound Upper GI Video Scope (Convex Array Type), EG36-J10UR Ultrasound Upper GI Video Scope (Radial Array Type), EG38-J10UT Ultrasound Upper GI Video Scope (Convex Array Type), and PENTAX Medical Ultrasound Video Bronchoscope EB19-J10U

Indications for Use *(Describe)*
The PENTAX Medical EG-J10U Endoscopic Ultrasound System is intended to provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the Upper Gastrointestinal Tract including but not restricted to the organs, tissues, and subsystems: Esophagus, Stomach, Duodenum 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.

The PENTAX Medical Ultrasound Video Bronchoscope EB19-J10U is intended to provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the Pulmonary Track including but not restricted to organs, tissues, and subsystem: Nasal Passage, Pharynx, Larynx, 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 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

a. Owner/Company name, address

PENTAX of America, Inc.

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b. Contact/Application Correspondent

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c. Date prepared

October 19, 2020

d. Name of device

This submission includes the following two devices in accordance with FDA guidance entitled "Bundling Multiple Devices or Multiple Indications in a Single Submission."

Device 1

Trade Name: PENTAX Medical EG-J10U Endoscopic Ultrasound System - EG34-J10U Ultrasound Upper GI Video Scope (Convex Array Type), EG36-J10UR Ultrasound Upper GI Video Scope (Radial Array Type), EG38-J10UT Ultrasound Upper GI Video Scope (Convex Array Type)

Regulation Name: Endoscope and accessories
Regulation Number: 21 CFR Part 876.1500
Regulation Class: II

Product Code: ODG
Subsequent Product Code: ITX
Classification Panel: Gastroenterology/Urology

Hereinafter, the Proposed Device is called as “PENTAX Medical EG-J10U Endoscopic Ultrasound System (Proposed)” in this submission.

Device 2

Trade Name: PENTAX Medical Ultrasound Video Bronchoscope EB19-J10U

Regulation Name: Bronchoscope (Flexible or Rigid) and Accessories

Regulation Number: 21 CFR Part 874.4680,

Regulation Class: II
Product Code: EOQ, ITX

Classification Panel: Ear Nose & Throat

Hereinafter, the Proposed Device is called as “PENTAX Medical Ultrasound Video Bronchoscope (Proposed)” in this submission because the predicate device has the same trade name.

e. Predicate device

Predicate device for PENTAX Medical EG-J10U Endoscopic Ultrasound System (Proposed) is as follows.

Trade Name: PENTAX Medical EG-J10U Endoscopic Ultrasound System - EG34-J10U Ultrasound Upper GI Video Scope (Convex Array Type), EG36-J10UR Ultrasound Upper GI Video Scope (Radial Array Type), EG38-J10UT Ultrasound Upper GI Video Scope (Convex Array Type)

510(k) Number: K200090
Regulation Name: Endoscope and accessories

Regulation Number: 21 CFR Part 876.1500

Regulation Class: II
Product Code: ODG
Subsequent Product Code: ITX
Classification Panel: Gastroenterology/Urology

Predicate device for PENTAX Medical Ultrasound Video Bronchoscope (Proposed) is as follows.

Trade Name: PENTAX Medical Ultrasound Video Bronchoscope EB19-J10U

510(k) Number: K183516
Regulation Name: Bronchoscope (Flexible or Rigid) and Accessories
Regulation Number: 21 CFR Part 874.4680
Regulation Class: II
Product Code: EOQ, ITX
Classification Panel: Ear Nose & Throat

f. Description of the device

PENTAX Medical EG-J10U Endoscopic Ultrasound System (Proposed)

The PENTAX Medical EG-J10U Endoscopic Ultrasound System (Proposed) includes three endoscope models EG34-J10U, EG36-J10UR, and EG38-J10UT Ultrasound Upper GI Video Scopes, and is used to provide visualization of, and therapeutic access to, the upper gastrointestinal tract. They are used with FDA cleared PENTAX Medical Video Processors (a software-controlled device) and FDA cleared Hitachi Ultrasound Scanners (a software-controlled device). The endoscopes have a flexible insertion tube, a control body, PVE umbilical connector, and ultrasound scanner umbilical connector. The PVE umbilical connector will be attached to the Video Processor and has connections for illumination, video signals, air, water, and suction.

The ultrasound scanner umbilical connector will be attached to the ultrasound scanner unit. A sterile, single use disposable natural rubber latex balloon is fitted over the convex array ultrasound transducer prior to the procedure. During an ultrasound endoscopy procedure, the latex balloon is inflated with water. The water that is contained within the balloon creates a water field that covers the transducer. The water field enables more effective transport of ultrasonic pulses from the ultrasound transducer to the target anatomical site and back to the ultrasound transducer.

The control body includes controls for up/ down/ left/ right angulation, air/ water delivery, and an accessory inlet port. The endoscope contains light carrying bundles to illuminate the body cavity, a charge coupled device (CCD) to collect endoscopic image data, and a linear or radial array ultrasound transducer to collect ultrasonic image data. The instrument contains a working

channel through which biopsy devices, or other devices, may be introduced.

The video processor contains a lamp that provides white light and is focused at the PVE connector light guide prong. The endoscope light carrying bundles present the light to the body cavity and the CCD collects endoscopic image data. Image data and other screen display information are formatted and presented to the video outputs of the video processor for display.

The ultrasound transducer delivers ultrasonic pulses, reflections of the pulses are received, and the signals are passed to the ultrasound scanner for processing and display. EG34-J10U, EG36-J10UR, and EG38-J10UT Ultrasound Upper GI Video Scopes are connected to the ultrasound scanner ARIETTA 70 and the ALOKA ARIETTA 850 via the scanning unit connector of the endoscope directly to the probe connector of the scanning unit. In order to connect to the Preirus scanning unit, junction box PUN-JBP1 is required to connect the scanning unit connector to the probe connector.

The instrument is immersible (with the use of supplied cleaning accessories) except for the ultrasound scanner connector (as described in the endoscope Operators Manual cleaning instructions).

PENTAX Medical Ultrasound Video Bronchoscope EB19-J10U (Proposed)

The PENTAX Medical Ultrasound Video Bronchoscope EB19-J10U (Proposed) connects with a video processor and an ultrasound scanner, both of which are software-controlled devices.

The endoscope has a flexible insertion tube, a control body, PVE connector, and scanning unit connector. The PVE connector attaches to the video processor and has connections for illumination and video signals. The ultrasound umbilical connector attaches to the ultrasound scanner unit.

The control body includes remote buttons for functions assigned from the video processor. It also includes controls for up/down angulation or neutral position, suction control, and ports for manual balloon insufflation/evacuation, and an accessory inlet.

The endoscope contains light carrying bundles to illuminate the body cavity, a charge coupled device (CCD) to collect endoscopic image data, and a convex array ultrasound transducer to collect ultrasonic image data. The instrument contains a working channel through which biopsy devices, or other devices may be introduced. The video processor contains a lamp that provides white light focused at the endoscope PVE connector light guide prong. The endoscope light carrying bundles present the light to the body cavity and the CCD collects endoscopic image

data. Image data and other screen display information are formatted and presented to the video outputs of the video processor for display.

The ultrasound transducer delivers ultrasonic pulses, reflections of the pulses are received and the signals are passed to the ultrasound scanner for processing and display. The instrument is immersible (with the use of supplied cleaning accessories). EB19-J10U is connected to the ultrasound scanners ARIETTA 70, ALOKA ARIETTA 850, and Noblus via the scanning unit connector of the endoscope directly to the probe connector of the scanning unit. In order to connect to the Preirus scanning unit, junction box PUN-JBP1 is required to connect the scanning unit connector to the probe connector.

g. Indications for Use Statement

The PENTAX Medical EG-J10U Endoscopic Ultrasound System is intended to provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the Upper Gastrointestinal Tract including but not restricted to the organs, tissues, and subsystems: Esophagus, Stomach, Duodenum 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.

The PENTAX Medical Ultrasound Video Bronchoscope EB19-J10U is intended to provide optical visualization of, ultrasonic visualization of, and therapeutic access to, the Pulmonary Track including but not restricted to organs, tissues, and subsystem: Nasal Passage, Pharynx, Larynx, 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 patient populations.

h. Comparative Information

Regarding the design, the only difference between the PENTAX Medical EG-J10U Endoscopic Ultrasound System (Proposed) and the predicate (K200090) is the addition of compatibility with the diagnostic ultrasound system ALOKA ARIETTA 850 (K183456) to the predicate device (K200090).

Similarly, the only difference between the PENTAX Medical Ultrasound Video Bronchoscope EB19-J10U (Proposed) and the predicate (K183516) is the addition of compatibility with the diagnostic ultrasound system ALOKA ARIETTA 850 (K183456) to the predicate device (K183516).

As there is commonality in the devices, proposed design changes, and method of evaluation;

changes to the K200090 and K183516 have been bundled in this submission according to the FDA guidance, “Bundling Multiple Devices or Multiple Indications in a Single Submission.”

Performance testing was conducted to support the proposed modifications of the subject devices, and it was determined that the proposed modifications do not raise issues regarding safety and effectiveness, or significantly change the performance, function, or general intended use of the devices.

Performance testing was performed to support the modifications of the proposed devices.

Minor revisions were made to the labeling, which included the addition of the ALOKA ARIETTA 850 (K183456) as a compatible scanner, and conformance to IEC 60601-1-2:2014.

i. Performance data

Our risk analysis identified the following risks and verification/validation activities for mitigation of risks regarding the addition of the ALOKA ARIETTA 850 (K183456) as a compatible scanner.

Table 6.1 Risks and Verification/Validation activities

	Risks	**Verification / Validation Methods**
I	Thermal injury(ies) to a patient, caused by the high temperature at the distal end of ultrasound scope, due to the excessive ultrasonic energy.	Measure distal end temperature
2	Electrical shock(s) to a patient, caused by the increased leak current from ultrasound scope, due to the excessive ultrasound energy.	Measure leak current
3	Incorrect performance(s) of endoscopic system, caused by electromagnetic irradiation from a connection part of the ultrasound scanning unit.	Measure electromagnetic irradiation
4	Ultrasonic performance of the new combinations is insufficient	Measure acoustic output of new combinations
5		Measure doppler sensitivity of new combinations

1. Thermal injury(ies) to a patient, caused by the high temperature at the distal end of ultrasound scope, due to excessive ultrasonic energy.

   Testing according to IEC 60601-2-37: 2007 +A l : 2015 of Electrical safety standard *(Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential pe1formance of ultrasonic medical diagnostic and monitoring equipment)* was conducted and it was confirmed that the ultrasound output power is properly adjusted and that the temperature at the distal end does not reach a point which would create thermal injuries.

2. Electrical shock(s) to a patient, caused by the increased leakage current from ultrasound scope, due to excessive ultrasound energy.

   Testing according to IEC 60601-2-37: 2007 of Electrical safety standard *(Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment)* was conducted, and it was confirmed that the ultrasound output power is properly adjusted and that the leakage current satisfies the standard.

   IEC 60601-2-37:2007 has been superseded with IEC 60601-2-37: 2007+A1: 2015, which is currently recognized by the FDA as a consensus standard. However, there is no difference in Clause 201.8, “Protection Against Electrical Hazards from ME Equipment” between the 2007 and the 2015 editions of the IEC standard.

3. Incorrect performance(s) of the endoscopic system, caused by electromagnetic irradiation from a connection part of the ultrasound scanning unit.

   Testing according to IEC 60601-1-2: 2014 of EMD standard *(Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests)* was conducted and it was confirmed that electromagnetic irradiation from the connection part satisfied the standard.

4. Ultrasonic performance of the new combinations is insufficient.

   Verification test to measure acoustic output of the new combinations was performed in accordance with FDA guidance, “Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound systems and Transducers” and doppler sensitivity of the new combinations by methods used to evaluate the ARIETTA 70 combinations in K200090 and K183516. The test results passed criteria and confirmed that the new combinations are acceptable.

The results of the above testing did not raise any new questions or concerns regarding safety and effectiveness.

j. Conclusion

PENTAX Medical concludes that the PENTAX Medical EG-J10U Endoscopic Ultrasound System (Proposed) and the PENTAX Medical Ultrasound Video Bronchoscope (Proposed) are substantially equivalent to the predicates (K200090) and (K183516), respectively.