Olympus Medical Systems Corp.
% Lisa Boyle
RA Program Manager
Olympus Corporation of the Americas
3500 Corporate Parkway
PO Box 610
Center Valley, Pennsylvania 18034-0610

November 9, 2020

Re: K203128
Trade/Device Name: EVIS EUS ENDOSCOPIC ULTRASOUND CENTER OLYMPUS EU-ME2/ EVIS EUS ENDOSCOPIC ULTRASOUND CENTER OLYMPUS EU-ME2 PREMIER PLUS
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, ODG
Dated: September 30, 2020
Received: October 19, 2020

Dear Lisa Boyle:

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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K203128

Device Name
EVIS EUS ENDOSCOPIC ULTRASOUND CENTER OLYMPUS EU-ME2/
EVIS EUS ENDOSCOPIC ULTRASOUND CENTER OLYMPUS EU-ME2 PREMIER PLUS

Indications for Use *(Describe)*
This ultrasound center is intended to be used with Olympus ultrasound endoscopes, Olympus ultrasound probes or Olympus esophageal ultrasound probes to observe and to store real-time ultrasound images and indicated for use within the gastrointestinal (GI) tract, biliary and pancreatic ducts and surrounding organs, airways and tracheobronchial tree, and urinary tract.

<Modes of operation>
B, PWD (Pulsed Wave Doppler), Color Doppler (including Power Doppler), Combined (combination of each operating mode) and other (3-D Imaging and Harmonic Imaging*).
*Only for the EU-ME2 PREMIER PLUS.

<Operator qualifications>
Appropriately-trained healthcare professional.

<Device use settings>
Hospital.

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.

Date Prepared: September 30, 2020

510(k) Summary

K203128

1. GENERAL INFORMATION

■ 510(k) Submitter: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-machi, Hachioji-shi, Tokyo 192-8507 Japan

■ Contact Person: Lisa M. Boyle
Olympus Corporation of the Americas
3500 Corporate Parkway PO Box 610
Center Valley, PA 18034-0610, USA
Phone: 484-896-3676
Fax: 484-896-7128
Email: lisa.boyle@olympus.com

■ Manufacturing site: Shirakawa Olympus Co., Ltd.
3-1 Okamiyama, Odakura, Nishigo-mura,
Nishishirakawa-gun, Fukushima 961-8061, Japan

2. DEVICE IDENTIFICATION

Device Name:	Model Name:
EVIS EUS ENDOSCOPIC ULTRASOUND CENTER	OLYMPUS EU-ME2
EVIS EUS ENDOSCOPIC ULTRASOUND CENTER	OLYMPUS EU-ME2 PREMIER PLUS

■ Accessories included in the subject device: Keyboard MAJ-1995
ULTRASOUND CABLE MAJ-2056

■ Common Name: Diagnostic Ultrasound System

■ Regulation Number:
892.1550 Ultrasonic pulsed doppler imaging system
892.1560 Ultrasonic pulsed echo imaging system
892.1570 Diagnostic ultrasonic transducer
876.1500 Endoscope and Accessories

■ Regulatory Class: II

■ Product Code: IYN: System, Imaging, Pulsed Doppler, Ultrasonic
IYO: System, Imaging, Pulsed Echo, Ultrasonic
ITX: Transducer, Ultrasonic, Diagnostic
ODG: Endoscopic ultrasound system, Gastroenterology-urology

■ Classification Panel: Radiology

3. PREDICATE DEVICE

■ **Predicate device**

Subject device name	Predicate device name	510(k) Submitter	510(k) No.
EVIS EUS ENDOSCOPIC ULTRASOUND CENTER OLYMPUS EU-ME2	ENDOSCOPIC ULTRASOUND CENTER EU-Y0006	OLYMPUS MEDICAL SYSTEMS CORP.	K121564
EVIS EUS ENDOSCOPIC ULTRASOUND CENTER OLYMPUS EU-ME2 PREMIER PLUS	ENDOSCOPIC ULTRASOUND CENTER EU-Y0008	OLYMPUS MEDICAL SYSTEMS CORP.	K130058
MAJ-1995 Keyboard	MAJ-Y0140 Keyboard	OLYMPUS MEDICAL SYSTEMS CORP.	K121564
MAJ-2056 ULTRASOUND CABLE	XMAJ-1597 ULTRASONIC CABLE	OLYMPUS MEDICAL SYSTEMS CORP.	K070983

4. DEVICE DESCRIPTION

■ **General Description of the subject device**

EVIS EUS ENDOSCOPIC ULTRASOUND CENTER OLYMPUS EU-ME2

The subject system (OLYMPUS EU-ME2) combined with Ultrasound videoscopes or Ultrasound probes to make an endoscopic ultrasound imaging system that can acquire and display high-resolution and high-penetration, real-time ultrasound images of the target organs.

The subject system has modes of B, PWD, Color Doppler, Combined (combination of each operating mode) and other (3-D Imaging).The subject system has no Harmonic Imaging function compared to the predicate device.

The subject system provides measurements and calculations of distance, area, circumference, volume, time, and blood velocity. It also allows for the storage and retrieval of images for reviewing and printing.
The subject system enables the user to print and record images to an external recording device.
The subject system can identify and recognize the compatible Olympus transducers and display endoscopic and ultrasound images.
The basic design, system configuration, general operation and user interface of this subject system is substantially equivalent to the predicate devices.

EVIS EUS ENDOSCOPIC ULTRASOUND CENTER OLYMPUS EU-ME2 PREMIER PLUS

The subject system (OLYMPUS EU-ME2 PREMIER PLUS) combined with Ultrasound videoscopes or Ultrasound probes to make an endoscopic ultrasound imaging system that can acquire and display high-resolution and high-penetration, real-time ultrasound images of the target organs.
The subject system has modes of B, PWD, Color Doppler, Combined (combination of each operating mode), other (3-D Imaging and Harmonic Imaging) and Elastography function which visualizes the amount of strain in tissue (hardness of tissue) during compression and retraction.
The subject system provides measurements and calculations of distance, area, circumference, volume, time and blood velocity. It also allows for the storage and retrieval of images for reviewing and printing.
The subject system enables the user to print and record images to an external recording device. Additionally, the subject system enables the user to record movies to internal memory.
The subject system can identify and recognize compatible Olympus transducers and display endoscopic and ultrasound images.
The basic design, system configuration, general operation, and user interface of this subject system is substantially equivalent to the predicate devices.

5. INDICATIONS FOR USE

EVIS EUS ENDOSCOPIC ULTRASOUND CENTER OLYMPUS EU-ME2/
EVIS EUS ENDOSCOPIC ULTRASOUND CENTER OLYMPUS EU-ME2 PREMIER PLUS

This ultrasound center is intended to be used with Olympus ultrasound endoscopes, Olympus ultrasound probes or Olympus esophageal ultrasound probes to observe and to store real-time ultrasound images and indicated for use within the gastrointestinal (GI) tract, biliary and pancreatic ducts and surrounding organs, airways and tracheobronchial tree, and urinary tract.

<Modes of operation>
B, PWD (Pulsed Wave Doppler), Color Doppler (including Power Doppler), Combined (combination of each operating mode) and other (3-D Imaging and Harmonic Imaging*).
*Only for the EU-ME2 PREMIER PLUS.

<Operator qualifications>
Appropriately-trained healthcare professional.

<Device use settings>
Hospital.

6. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEVICE

EVIS EUS ENDOSCOPIC ULTRASOUND CENTER OLYMPUS EU-ME2
The subject device has the same fundamental scientific technology, principle of operation and energy source as the legally marketed ENDOSCOPIC ULTRASOUND CENTER (EU-Y0006) in K121564, with the following modifications. A side by side comparison of the subject device and the predicate device is provided in the table below.

Table 1: Comparison of the Subject and Predicate Device

Item	Subject Device OLYMPUS EU-ME2	Predicate Device EU-Y0006 (K121564)
Indications for Use	This ultrasound center is intended to be used with Olympus ultrasound endoscopes, Olympus	This ultrasound center is intended to be used with Olympus ultrasound endoscopes, Olympus

Item	Subject Device OLYMPUS EU-ME2	Predicate Device EU-Y0006 (K121564)
	ultrasound probes or Olympus esophageal ultrasound probes to observe and to store real-time ultrasound images and indicated for use within the gastrointestinal (GI) tract, biliary and pancreatic ducts and surrounding organs, airways and tracheobronchial tree, and urinary tract <Modes of operation> B, PWD (Pulsed Wave Doppler), Color Doppler (including Power Doppler), Combined (combination of each operating mode) and other (3-D Imaging and Harmonic Imaging*). *Only for the EU-ME2 PREMIER PLUS. <Operator qualifications> Appropriately-trained healthcare professional. <Device use settings> Hospital.	ultrasound probes or Olympus esophageal ultrasound probes to observe and to store real-time ultrasound images and indicated for use within the gastrointestinal (GI) tract, biliary and pancreatic ducts and surrounding organs, airways and tracheobronchial tree, and urinary tract.
Mode	B	B
	PW Doppler(PWD)	PW Doppler(PWD)
	Color flow (Color Doppler)	Color flow (Color Doppler)
	Power flow (Power Doppler)	Power flow (Power Doppler)
	Not applicable	Tissue harmonic echo (Harmonic Imaging)
	Combined	Combined
	3-D Imaging	3-D Imaging

Item	Subject Device OLYMPUS EU-ME2	Predicate Device EU-Y0006 (K121564)
Patient Contact Material	None	None
510(k) track	Track 3	Track 3
Outer Dimensions (mm)	Main Unit : 445(w) X 495(d) X 184(h) Keyboard : 392(w) X 207(d) X 39(h)	Main Unit : 445(w) X 500(d) X 183(h) Keyboard : 392(w) X 207(d) X 42(h)
Weight (kg)	22.5	22

EVIS EUS ENDOSCOPIC ULTRASOUND CENTER OLYMPUS EU-ME2 PREMIER PLUS

The subject device has the same fundamental scientific technology, principle of operation and energy source as the legally marketed ENDOSCOPIC ULTRASOUND CENTER (EU-Y0008) in K130058, with the following modifications. A side by side comparison of the subject device and the predicate device is provided table below.

Table 2: Comparison of the Subject and Predicate Device

Item	Subject Device OLYMPUS EU-ME2 PREMIER PLUS	Predicate Device EU-Y0008 (K130058)
Indications for Use	This ultrasound center is intended to be used with Olympus ultrasound endoscopes, Olympus ultrasound probes or Olympus esophageal ultrasound probes to observe and to store real-time ultrasound images and indicated for use within the gastrointestinal (GI) tract, biliary and pancreatic ducts and surrounding organs, airways and tracheobronchial tree, and urinary tract. <Modes of operation> B, PWD (Pulsed Wave Doppler), Color Doppler (including Power Doppler),	This ultrasound center is intended to be used with Olympus ultrasound endoscopes, Olympus ultrasound probes or Olympus esophageal ultrasound probes to observe and to store real-time ultrasound images and indicated for use within the gastrointestinal (GI) tract, biliary and pancreatic ducts and surrounding organs, airways and tracheobronchial tree, and urinary tract.

Item	Subject Device OLYMPUS EU-ME2 PREMIER PLUS	Predicate Device EU-Y0008 (K130058)
	Combined (combination of each operating mode) and other (3-D Imaging and Harmonic Imaging*). *Only for the EU-ME2 PREMIER PLUS. <Operator qualifications> Appropriately-trained healthcare professional. <Device use settings> Hospital.	
Mode	B	B
	PW Doppler(PWD)	PW Doppler(PWD)
	Color flow (Color Doppler)	Color flow (Color Doppler)
	Power flow (Power Doppler)	Power flow (Power Doppler)
	Tissue harmonic echo (Harmonic Imaging)	Tissue harmonic echo (Harmonic Imaging)
	Combined	Combined
	3-D Imaging	3-D Imaging
Image function	Elastography	Elastography
Patient Contact Material	None	None
510(k) track	Track 3	Track 3
Outer Dimensions (mm)	Main Unit : 445(w) X 495(d) X 184(h) Keyboard : 392(w) X 207(d) X 39(h)	Main Unit : 445(w) X 500(d) X 183(h) Keyboard : 392(w) X 207(d) X 42(h)
Weight (kg)	22.5	22

7. PERFORMANCE DATA

The following performance testing was conducted in support of the substantial equivalence determination.

7.1 Software verification and validation testing

Software verification and validation testing was conducted and documentation is 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" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".

7.2 Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing was conducted in accordance with the ANSI/AAMI ES 60601-1:2005/(R) 2012 and A1:2012, and IEC 60601-2-18:2009 standards for safety, and IEC 60601-1-2:2014 standards for EMC and IEC 60601-2-37:2015.

7.3 Performance testing - Animal

No animal study was performed to demonstrate substantial equivalence.

7.4 Performance testing - Clinical

No clinical study was performed to demonstrate substantial equivalence.

7.5 Risk management

Risk management was performed in accordance with ISO 14971:2007, and a human factors validation was conducted in accordance with the FDA Guidance, "Applying Human Factors and Usability Engineering to Medical Devices". The design verification tests and their acceptance criteria were identified and performed as a result of this risk management.

8. CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate device, the subject device raises no new issue of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, effectiveness and performance.