January 17, 2025

Olympus Medical Systems Corporation
% Wendy Perreault
Regulatory Affairs SME Consultant
Olympus Surgical Technologies of the Americas
800 West Park Drive
Westborough, MA 01581

Re: K243502
Trade/Device Name: EVIS EUS Endoscopic Ultrasound Center Olympus EU-ME3 (Olympus EU-ME3)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, ODG
Dated: November 11, 2024
Received: November 12, 2024

Dear Wendy Perreault:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Marjan Nabili -S for

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243502

Device Name

EVIS EUS ENDOSCOPIC ULTRASOUND CENTER OLYMPUS EU-ME3 (OLYMPUS EU-ME3)

Indications for Use *(Describe)*

EVIS EUS ENDOSCOPIC ULTRASOUND CENTER OLYMPUS EU-ME3 is intended to be used with Olympus ultrasound endoscopes and Olympus ultrasound probes to observe real-time ultrasound images and is indicated for use within the gastrointestinal (GI) tract, biliary and pancreatic ducts and surrounding organs, intraluminal ultrasound for airways, tracheobronchial tree, trans-rectal, trans-urethral, and trans-esophageal (non-cardiac).

<Modes of Operation>
B mode, PWD (Pulsed Wave Doppler) mode, Color Doppler (including Power Doppler) mode, combinations of each mode of operation (B mode, PWD mode, Color Doppler mode) and Other (Harmonic Imaging, Elastography and Shear Wave Speed Measurement [Shear Wave Quantification]).

<Operator Qualifications>
Appropriately trained healthcare professionals.

<Device Use Settings>
Hospital or Patient care facility.

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.

510(k) Summary: K243502

1. COMPANY INFORMATION

- **Applicant**

OLYMPUS MEDICAL SYSTEMS CORPORATION
2951 Ishikawa-cho, Hachioji-shi
Tokyo 192-8507, Japan
FDA Establishment Registration #: 8010047

- **Official Correspondent**

Wendy Perreault
c/o Olympus Surgical Technologies of the Americas
800 West Park Drive
Westborough, MA 01581
Cell: 404.542.5854
Email: wendy.perreault@olympus.com

- **Manufacturing Site**

SHIRAKAWA OLYMPUS CO., LTD.
3-1 Okamiyama, Odakura
NISHIGO-MURA
NISHISHIRAKAWA-GUN Fukushima, JAPAN 961-8061

- **Date Prepared:** January 16, 2025

2. PRODUCT INFORMATION

Trade Name: EVIS EUS ENDOSCOPIC ULTRASOUND CENTER OLYMPUS EU-ME3 (OLYMPUS EU-ME3)

Common Name: Ultrasonic Pulsed Doppler Imaging System

Classification Name: System, Imaging, Pulsed Doppler, Ultrasonic

Regulation Number: 892.1550

Regulatory Class: II

Product Code(s): IYN, IYO, ITX, ODG

Classification Panel: Radiology

3. PREDICATE DEVICE

The Subject device is equivalent to the Predicate device listed below in **Table 1**.

Table 1: Predicate Device

Device name	510(k) Submitter	510(k) No.
OLYMPUS EU-ME2 Premier Plus	OLYMPUS MEDICAL SYSTEMS CORP.	K203128

A Reference device (shown in **Table 2**) was included in the submission to support the Subject device Strain Ratio, Strain Histogram, Shear Wave Quantification and Contrast Hamonic Echo functions/modes:

Table 2: Reference Device

Device name	510(k) Submitter	510(k) No.
Hitachi ALOKA ARIETTA 850	Hitachi, Ltd.	K183456

4. DEVICE DESCRIPTION

The EVIS EUS ENDOSCOPIC ULTRASOUND CENTER OLYMPUS EU-ME3 system (including KEYBOARD MAJ-2380), when combined with compatible ultrasound video scopes or ultrasound probes, makes an endoscopic ultrasound imaging system that can acquire and display and record real-time ultrasound images of the target tissue or organs. It supplies the driving voltage to the ultrasound transducers to generate ultrasound waves. Using these transducers, the Subject system can display endoscopic and ultrasound images to provide measurements and calculations of distance, area, circumference, time, blood velocity, strain ratio, strain histogram and shear wave speed of the targeted areas. It also allows 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 accessories submitted for clearance with the EU-ME3 that may be purchased separately include three (3) Software Options, which unlock software that is pre-installed on the EU-ME3 (for Contrast Harmonic Echo [MAJ-2381], Elastography [MAJ-2382] and Shear Wave Quantification [MAJ-2383]).

5. INDICATIONS FOR USE

EVIS EUS ENDOSCOPIC ULTRASOUND CENTER OLYMPUS EU-ME3 is intended to be used with Olympus ultrasound endoscopes and Olympus ultrasound probes to observe real-time ultrasound images and is indicated for use within the gastrointestinal (GI) tract, biliary and pancreatic ducts and surrounding organs, intraluminal ultrasound for airways, tracheobronchial tree, trans-rectal, trans-urethral, and trans-esophageal (non-cardiac).

<Modes of Operation>
B mode, PWD (Pulsed Wave Doppler) mode, Color Doppler (including Power Doppler) mode, combinations of each mode of operation (B mode, PWD mode, Color Doppler mode) and Other (Harmonic Imaging, Elastography and Shear Wave Speed Measurement [Shear Wave Quantification]).

<Operator Qualifications>
Appropriately trained healthcare professionals.

<Device Use Settings>
Hospital or Patient care facility.

6. COMPARISON OF INDICATIONS FOR USE

The Indications for Use for the Subject and Predicate device are similar but not identical. The Subject device Indication for Use references "intraluminal ultrasound for airways and tracheobronchial tree and trans-rectal, trans-urethral, and trans-esophageal (non-cardiac) clinical applications" - this description was not specifically in the Indications for Use for the Predicate but were listed as clinical applications for the Predicate device in K203128. The Subject device includes Shear Wave Speed Measurement (Shear Wave Quantification) as a listed Mode of Operation which was not included with the Predicate device, and the Predicate device included 3-D imaging, which is not provided for the Subject device. Note that although Elastography was a Mode of Operation included with the Predicate device, it was not listed in the Indications for Use as such in K203128 because Elastography was considered an Image Function at the time of submission of the Predicate, rather than a Mode of Operation. The Subject Indications for Use includes a Patient Care Facility as a specified Device Use Setting, in addition to the Hospital Setting which is common to both the Subject and the Predicate. The differences between the Subject and Predicate device Indications for Use do not constitute a new intended use for the Subject device.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Subject and Predicate device share the same technological characteristics (i.e., design,

material, principle of operation, and energy source). Acoustic output of both devices is ≤720mW/cm^2; both offer Measurement and Calculation functions, Time-intensity-curve (TIC) Analysis function, Electronic and Mechanical scanning, and image storage and review and printing and recording capabilities. The Subject device also provides Strain Ratio/Strain Histogram and Shear Wave Quantification (Shear Wave Speed Measurement), as provided by the Reference device. Both the Subject and Predicate devices provide B, Pulsed Wave Doppler, Color Flow (Color Doppler), Power Flow (Power Doppler), Combined, and Tissue Harmonic Echo (THE) (Harmonic Imaging) modes. The Subject device also provides Contrast Harmonic Echo (Harmonic Imaging) mode, as provided by the Reference device.

8. SUMMARY OF NON-CLINICAL PERFORMANCE DATA

The following non-clinical testing was completed for the Subject device:

- Bench testing, including Acoustic Output; Clinical Measurement Accuracy of Strain Ratio Measurement, Distance, Circumference and Area, Velocity Measurement in SWQ Function, Time, and Velocity; Strain Ratio Function on Elastography (ELST); Visualization of the Amount of Strain on ELST; and Contrast Harmonic Echo (CHE).
- Human Factors Evaluation in compliance with ANSI AAMI IEC 62366-1
- Cleaning/disinfection validation in compliance with ISO 17664-1
- Software and Cybersecurity testing in compliance with
    - ANSI AAMI ISO 14971
    - ANSI AAMI IEC 62304
- Electrical Safety and EMC testing in compliance with
    - IEC 60601-1
    - ANSI AAMI IEC 60601-1-2
    - IEC 60601-1-6
    - IEC 60601-2-18
    - IEC 60601-2-37
    - IEC 60601-4-2

Completed nonclinical testing supports compliance of the Subject device with FDA Guidance Document *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers - Guidance for Industry and Food and Drug Administration Staff* (issued February 21, 2023).

The nonclinical testing demonstrated that the device is as safe, as effective, and performs as well or better than the legally marketed Predicate.

9. SUMMARY OF CLINICAL PERFORMANCE DATA

No clinical data were collected to support performance of the Subject device.

10. CONCLUSION

Based on the results of the comparison of the indications for use, technological characteristics, and performance testing of the Subject and Predicate device, the Subject EVIS EUS ENDOSCOPIC ULTRASOUND CENTER OLYMPUS EU-ME3 raises no new issues of safety and effectiveness, and the device is substantially equivalent to the Predicate device.