July 11, 2025

Olympus Medical Systems Corporation
% Brenda Geary
Senior Manager Regulatory Affairs
Olympus Surgical Technologies of the Americas
800 West Park Drive
WESTBOROUGH MA 01581

Re: K250762
Trade/Device Name: Ultrasonic Probe UM-S20-17S (UM-S20-17S); Ultrasonic Probe UM-S20-20R (UM-S20-20R)
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: ITX, EOQ
Dated: June 11, 2025
Received: June 11, 2025

Dear Brenda Geary:

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)*

K250762

Device Name

ULTRASONIC PROBE UM-S20-17S (UM-S20-17S)
ULTRASONIC PROBE UM-S20-20R (UM-S20-20R)

Indications for Use *(Describe)*

The ULTRASONIC PROBE UM-S20-17S has been designed to be used with an endoscopic ultrasound center, a probe driving unit, and an endoscope for intraluminal ultrasonic imaging of the upper airways and tracheobronchial tree.

Modes of operation:
The Mode of Operation is B mode.

Operator qualifications:
Appropriately trained healthcare professionals.

Device use settings:
Healthcare facility

The ULTRASONIC PROBE UM-S20-20R has been designed to be used with an endoscopic ultrasound center, a probe driving unit, and an endoscope for intraluminal ultrasonic imaging of the upper airways and tracheobronchial tree.

Modes of operation:
The Mode of Operation is B mode.

Operator qualifications:
Appropriately trained healthcare professionals.

Device use settings:
Healthcare 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: K250762

1. COMPANY INFORMATION

- **Applicant**

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

- **Official Correspondent**

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- **Manufacturing Site**

SHIRAKAWA OLYMPUS CO., LTD.
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NISHIGO-MURA
NISHISHIRAKAWA-GUN Fukushima, JAPAN 961-8061

- **Date Prepared:** 9 July 2025

2. PRODUCT INFORMATION

Trade Name: ULTRASONIC PROBE UM-S20-17S (UM-S20-17S); ULTRASONIC PROBE UM-S20-20R (UM-S20-20R)

Common Name: Diagnostic Ultrasound Transducer

Classification Number: 21 CFR 892.1570, 21 CFR 874.4680

Product Code Names: Transducer, Ultrasonic Diagnostics; Bronchoscope (Flexible or Rigid) and Accessories
Product Codes: ITX, EOQ

Regulatory Class: II

Classification Panel: Radiology

3. PREDICATE DEVICE

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

Table 1: Predicate device for ULTRASONIC PROBE UM-S20-17S and UM-S20-20R

Device name	510(k) Submitter	510(k) No.
FUJIFILM Endoscopic Ultrasonic Probe (P2612S-L); Endoscopic Ultrasonic Probe (P2620S-L)	Fujifilm Healthcare Americas Corporation	K231666

The Predicate device has not been subject to a design-related recall.

The Reference device supporting the performance of the Subject devices is listed below in **Table 2.**

Table 2: Reference device for ULTRASONIC PROBE UM-S20-17S and UM-S20-20R

Device name	510(k) Submitter	510(k) No.
UM-3R Ultrasonic Probe	OLYMPUS MEDICAL SYSTEMS CORPORATION	K063683

4. DEVICE DESCRIPTION

The Ultrasonic Probes have been designed to be used with an Olympus Endoscopic Ultrasound Center, a Probe Driving Unit, other ancillary equipment and an endoscope for intraluminal ultrasonic imaging of the of the upper airways and tracheobronchial tree and surrounding organs.

Ultrasonic Probes UM-S20-17S and UM-S20-20R are designed to be used in conjunction with bronchoscopes. The Probes are inserted into the patient through a channel of the endoscope.

The Ultrasonic Probes consist of an insertion tube and a connector section. The connector section is connected to the Probe Driving Unit and the Probe Driving Unit is connected to the Ultrasound Center.
The Ultrasonic Probe sends and receives electrical signals to and from the Ultrasound Center through the Probe Driving Unit. The Probes use a 20MHz frequency piezoelectric transducer and produce B-mode scan. They produce 360-degree mechanical/radial sonograms.

The transducer is built into the insertion tube at the tip of the Probe. The transducer is rotated by the Probe Driving Unit within the insertion tube.

The transducer converts the electrical signal to the ultrasound wave, sends it to the object, receives the reflected wave from the object and converts it to the electrical signal. The electrical signal is input to the Endoscopic Ultrasound Center and the ultrasound image is generated by the Endoscopic Ultrasound Center.

UM-S20-17S and UM-S20-20R use direct contact method only.

The Subject devices submitted for clearance each include one (1) major component: the Ultrasonic Probe, which is packaged with a Probe Holder (MH-245) and a Water-resistant Cap (MH-244).

The target population for this device is Adults.

5. INDICATIONS FOR USE

- The ULTRASONIC PROBE UM-S20-17S has been designed to be used with an endoscopic ultrasound center, a probe driving unit, and an endoscope for intraluminal ultrasonic imaging of the upper airways and tracheobronchial tree.

  [Modes of operation]
  The Mode of Operation is B mode.

  [Operator qualifications]
  Appropriately trained healthcare professionals.

  [Device use settings]
  Healthcare facility

- The ULTRASONIC PROBE UM-S20-20R has been designed to be used with an endoscopic ultrasound center, a probe driving unit, and an endoscope for intraluminal ultrasonic imaging of the upper airways and tracheobronchial tree.

  [Modes of operation]
  The Mode of Operation is B mode.

  [Operator qualifications]

Appropriately trained healthcare professionals.

[Device use settings]
Healthcare facility

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Compared to the Predicate and Reference devices, the Subject devices offer similar functions. A detailed comparison of the technological characteristics of the devices is provided in **Table 3** below. These differences in technological characteristics do not raise new questions of safety or effectiveness.

Table 3: Subject, Predicate and Reference Device Comparison of Technological Characteristics

Item	Subject Devices (SD)		Predicate Device (PD)	Reference Device (RD)
	UM-S20-17S	**UM-S20-20R**	**FUJIFILM Endoscopic Ultrasonic Probe (P2612S-L); Endoscopic Ultrasonic Probe (P2620S-L)**	**UM-3R**
Manufacturer	OLYMPUS MEDICAL SYSTEMS CORPORATION	OLYMPUS MEDICAL SYSTEMS CORPORATION	Fujifilm Healthcare Americas Corporation	OLYMPUS MEDICAL SYSTEMS CORPORATION
510(k) #	N/A	N/A	K231666	K063683
Classification Product Code	ITX	ITX	ITX	IYN
Subsequent Product Code(s)	EOQ	EOQ	N/A	ITX, IYO, ODG
Indications for Use	The ULTRASONIC PROBE UM-S20-17S has been designed to be used with an endoscopic ultrasound center, a probe driving unit, and an endoscope for intraluminal ultrasonic imaging of the upper airways and tracheobronchial tree. [Modes of operation] The Mode of Operation is B mode. [Operator qualifications] Appropriately trained healthcare professionals. [Device use settings] Healthcare facility	The ULTRASONIC PROBE UM-S20-20R has been designed to be used with an endoscopic ultrasound center, a probe driving unit, and an endoscope for intraluminal ultrasonic imaging of the upper airways and tracheobronchial tree. [Modes of operation] The Mode of Operation is B mode. [Operator qualifications] Appropriately trained healthcare professionals. [Device use settings] Healthcare facility	This product is a medical ultrasonic probe. It is intended for the observation and diagnosis of the gastrointestinal tract and surrounding organs under the management of physicians at medical facilities. This product is intended for adults. Modes of Operation: B-mode Never use this product for any other purposes.	These instruments have been designed to be used with an Olympus Endoscopic Ultrasound Center, a Water Supply Unit (For Ultrasonic Endoscope), a Probe Driving Unit, a Probe/Irrigation Plug and an endoscope for intralumenal ultrasonic imaging of the gastrointestinal tract and surrounding organs, the upper airways and tracheobronchial tree and the urinary organs.
Frequency	20 MHz	20 MHz	P2612S-L: 10MHz±15% P2620S-L: 17MHz±15%	20 MHz

Item	Subject Devices (SD)		Predicate Device (PD)	Reference Device (RD)
	UM-S20-17S	UM-S20-20R	FUJIFILM Endoscopic Ultrasonic Probe (P2612S-L); Endoscopic Ultrasonic Probe (P2620S-L)	UM-3R
Display mode	B-mode	B-mode	B-mode	B-mode
Compatible Endoscopic Ultrasound System	OLYMPUS : EU-ME2 EU-ME2 Premier Plus EU-ME3	OLYMPUS : EU-ME2 EU-ME2 Premier Plus EU-ME3	FUJIFILM Ultrasonic Processor SP-900	OLYMPUS XEU-M60A
Number of Transducers	1	1	-	1
Shape of Transducer	Rectangle	Rectangle	-	Rectangle
Size of Transducer	0.75 × 2.3mm	1.0 × 2.3mm	-	1.6 × 2.4mm
Scanning direction	Perpendicular to the direction of insertion	Perpendicular to the direction of insertion	-	Perpendicular to the direction of insertion
Scanning field of view (Scanning area)	360°	360°	-	360°
Frame rate	6.67rps	6.67rps	-	6.67rps
Axial resolution	2mm or less	2mm or less	1mm or less	2mm or less
Lateral resolution	2mm or less	2mm or less	3mm or less	2mm or less
Scanning method	Mechanical, radial scanning	Mechanical, radial scanning	Mechanical, radial scanning	Mechanical, radial scanning
Contact method	Direct contact method	Direct contact method	-	Direct contact method
	N/A	N/A	-	Sterile De-aerated water immersion method
	N/A	N/A	-	Balloon method (Balloon sheath [MH-246R] is necessary).
Insertion tube maximum outer diameter (mm)	ϕ 1.45 (Distal end side 1085mm) ϕ 1.8 (Connector side)	ϕ 1.75 (Distal end side 850mm) ϕ 2.05 (Connector side)	2.6	ϕ 2.5
Insertion tube outer diameter (mm)	ϕ 1.4 (Distal end side 1085mm) ϕ 1.7 (Connector side)	ϕ 1.7 (Distal end side 850mm) ϕ 2.0 (Connector side)	2.5	ϕ 2.4

Item	Subject Devices (SD)		Predicate Device (PD)	Reference Device (RD)
	UM-S20-17S	**UM-S20-20R**	**FUJIFILM Endoscopic Ultrasonic Probe (P2612S-L); Endoscopic Ultrasonic Probe (P2620S-L)**	**UM-3R**
Ultrasonic medium	Liquid paraffin (High White 70)	Liquid paraffin (High White 70)	-	Liquid paraffin (High White 70)
Working length (mm)	2150	2050	2620	2050
Total length (mm)	2225	2140	-	2140
Sterilization method for reprocessing	ETO	ETO	ETO	N/A
Compatible Olympus Reprocessor for cleaning and disinfection	OER-Pro OER-Elite	OER-Pro OER-Elite	N/A	N/A
Electrical safety	Compliance to IEC 60601-1, IEC 60601-2-18, IEC 60601-2-37	Compliance to IEC 60601-1, IEC 60601-2-18, IEC 60601-2-37	Compliance to IEC 60601-1, IEC 60601-2-37	Compliance to IEC 60601-1, IEC 60601-2-18
EMC	Compliance to IEC 60601-1-2	Compliance to IEC 60601-1-2	Compliance to IEC 60601-1-2	Compliance to IEC 60601-1-2

7. SUMMARY OF NON-CLINICAL PERFORMANCE DATA

Results of the following testing support the safety and performance of the Subject devices and demonstrate their equivalence to the Predicate device and Reference device; all testing passed/met the acceptance criteria, demonstrated compliance with the cited standards and FDA Guidance shown below, and supported equivalent safety and performance to the Predicate and Reference devices:

- Performance Testing – Bench (including Acoustic Output in compliance with IEC 60601-2-37, IEC 62359, IEC 62127-1, and FDA Guidance: *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers - Guidance for Industry and Food and Drug Administration Staff* (February 21, 2023); Durability, Measurement Accuracy; and Human Use Factors following FDA Guidance Documents *Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff* (issued February 3, 2016) and *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff* (issued March 17, 2015).
- Biocompatibility Testing (ISO 10993-1; ISO 10993-5; ISO 10993-10; ISO 10993-12; ISO 10993-17; ISO 10993-18; ISO 10993-23)
- Reprocessing Validation (ISO 17664-1; AAMI TIR12; ANSI AAMI ST98; ANSI AAMI ST58; ISO 11135; ISO 11138-2)
- Electrical Safety/EMC Testing (IEC 60601-1; IEC ES60601-1; IEC 60601-1-2; IEC 60601-2-18; IEC 60601-2-37; IEC TR 60601-4-2)

8. SUMMARY OF CLINICAL PERFORMANCE DATA

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

9. CONCLUSION

The results of non-clinical performance testing demonstrate that the Subject devices are as safe and effective as the Predicate device to support a substantial equivalence determination.