Ultrasound Biotechnology (Shanghai) Co., Ltd.
℅ Yingnan Zhang
Vice President
Room 401, Floor 4, No. 1 Building, 269 Lianchuang Rd.
Pudong, Shanghai 200135
CHINA

December 21, 2023

Re: K231889
Trade/Device Name: Endoscopic Ultrasonic Diagnostic Equipment /Disposable Sterile Endoscopic Ultrasonic Probe (USW-S1,USW140-S20MS)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: November 17, 2023
Received: November 17, 2023

Dear Yingnan Zhang:

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.

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,

Yanna S. Kang -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231889

Device Name
Endoscopic Ultrasonic Diagnostic Equipment/ Disposable Sterile Endoscopic Ultrasonic Probe (USW-S1,USW140-S20MS)

Indications for Use *(Describe)*
Endoscopic Ultrasonic Diagnostic Equipment/Disposable Sterile Ultrasonic Probe is intended to be used in conjunction with ultrasound endoscopes to acquire and display real-time ultrasound images of the target organs. This device is indicated for intraluminal ultrasound imaging of the upper respiratory tract and bronchus, digestive tract, and hepatobiliary and pancreatic organs.

Mode of operation includes B mode. This device is intended for use by a qualified and trained healthcare professional in a hospital setting or medical clinic.

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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510(k) Summary

K231889

1. Submitter information

Applicant Name	ULTRASOUND BIOTECHNOLOGY (SHANGHAI) CO., LTD.
Applicant Address	Room 401, Floor 4, No. 1 Building, 269 Lianchuang Rd., Pudong, 200135 Shanghai, PR. China Shanghai 200135 China
Applicant Contact Telephone	021-50362882
Applicant Contact	Yingnan Zhang
Contact Email	zhangyingnan@ultrasoundmed.com.cn

2. Application correspondent

Company	Landlink Healthcare Technology (Shanghai) Co., Ltd.
Address	Room 1308, Baohua International Plaza, West Guangzhong Road 555, Jingan District
Contact person	Eric Zhang
Contact Email	eric.zhang@landlink-health.com

3. Device Name

Device Trade Name	Endoscopic Ultrasonic Diagnostic Equipment/ Disposable Sterile Endoscopic Ultrasonic Probe (USW-S1,USW140-S20MS)
Common Name	Ultrasonic pulsed echo imaging system, Diagnostic ultrasonic transducer
Regulation Number	892.1560 Ultrasonic pulsed echo imaging system 892.1570 Transducer, Ultrasonic, Diagnostic
Product Code	IYO:System, Imaging, Pulsed Echo, Ultrasonic ITX: Transducer, Ultrasonic, Diagnostic
Regulation Class	Class II
Classification Panel	Radiology

4. Legally Marketed Predicate Device

Predicate #	Predicate Trade Name	Product Code
K951994(Primary)	Olympus EU-M30 Endoscopic Ultrasound Center and ancillary equipment	IYO
K944610(secondary)	OLYMPUS ULTRASONIC PROBES	ITX

5. Device Description Summary

Endoscopic Ultrasonic Diagnostic Equipment consist of main unit, control panel, driver box, trolley, and display,it is used in conjunction with Disposable Sterile Endoscopic Ultrasonic Probe to acquire and display high-resolution and high-penetration,real-time ultrasound images of the target organs. Disposable Sterile Endoscopic Ultrasonic Probe is single-use.

The subject system only has B mode.

The subject system provide measurements and calculations of distance,area,circumference, 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 will be used with compatible endoscope system：

Bronchoscope System (EOS-H-01, Shanghai AnQin Medical Instrument Co.Ltd)cleared under K211169.

-working length maximum 600mm

-Insrument channel dimaeter minimum 1.7mm

6. Indications for Use

Endoscopic Ultrasonic Diagnostic Equipment/Disposable Sterile Ultrasonic Probe is intended to be used in conjunction with ultrasound endoscopes to acquire and display real-time ultrasound images of the target organs. This device is indicated for intraluminal ultrasound imaging of the upper respiratory tract and bronchus, digestive tract, and hepatobiliary and pancreatic organs.

Mode of operation includes B mode. This device is intended for use by a qualified and trained healthcare professional in a hospital setting or medical clinic.

7. Technological Comparison

Table 1 Comparison of the Subject and primary Predicate Device(host)

Item	Subject Device USW-S1	Primary Predicate Device EU-M30
Indications for Use	Endoscopic Ultrasonic Diagnostic Equipment/Disposable Sterile Ultrasonic Probe is intended to be used in conjunction with ultrasound endoscopes to acquire and display real-time ultrasound images of the target organs. This device is indicated for intraluminal ultrasound imaging of the upper respiratory tract and bronchus, digestive tract, and hepatobiliary and pancreatic organs. Modes of operation:B. Operator qualifications: Qualified and trained healthcare professional. Device use settings: Hospital or medical clinic.	Olympus EU-M30 Endoscopic Ultrasound Center is designed to be used inn combination with Olympus GF-UM20/JF-UM20/CF-UM20 ultrasonic endoscopes.Olympus UM-2R/UM-3R ultrasonic probes, and Olympus MH-908 esphageal ultrasonic probe for observation of real-time ultrasound images of upper GI tract,lower GI tract, and adjacent structures. Modes of operation:B. Operator qualifications: Appropriately-trained healthcare professional. Device use settings:Hospital.
Acoustic scanning format	Mechanical scan	
Measurement & Analysis	Distance, Circumference Length/Area	
Mode of operation	B	
Available Frequency	20 MHz	7.5, 12, 20 MHz
Display range	2cm	1,2, 3, 4, 6, 9, 12 cm

Table 2 Comparison of the Subject and Secondary Predicate Device(probe)

Specification	Subject Device USW140-S20MS Transducer	Secondary Predicate device UM-S20-17S (K944610)
Probe Type	Mechanic Radial scan	Mechanic Radial scan
Indications for Use	Endoscopic Ultrasonic Diagnostic Equipment/Disposable Sterile Ultrasonic Probe is intended to be used in conjunction with ultrasound endoscopes to acquire and display real-time ultrasound images of the target organs. This device is indicated for intraluminal ultrasound	UM-S20-17S is designed for use with Olympus endoscopic ultrasound system to observe and to store real-time ultrasound images and indicated for use within the gastrointestinal(GI) tract,biliary ,pancreatic ducts and surrounding organs,airways and

Specification	Subject Device USW140-S20MS Transducer	Secondary Predicate device UM-S20-17S (K944610)
	imaging of the upper respiratory tract and bronchus, digestive tract, and hepatobiliary and pancreatic organs. Modes of operation:B. Operator qualifications: Qualified and trained healthcare professional. Device use settings: Hospital or medical clinic.	tracheobronchial tree,and urinary tract. Modes of operation:B. Operator qualifications: Qualified and trained healthcare professional. Device use settings: Hospital or medical clinic.
Mode	Mode B	
Scanning method	Mechanical radial Scanning	
Ultrasonic frequency	20 MHz	
Effective length	1800 mm	2150 mm
Full length	1840 mm	2250 mm
Outer diameter of insertion tube	⌀ 1.4 (distal end 1085 mm) ⌀ 1.8 (proximal end)	⌀ 1.4 (distal end 1085 mm) ⌀ 1.7 (proximal end)
Maximum diameter of insertion portion	1.8 mm	1.8 mm
Array dimensions	N/A	N/A
Number of elements in the array	1	1
Single use/ Re-use	Single use	Re-use
Provided sterile or not	Sterile	Not

8. Non-Clinical Tests Summary

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

Acoustic output

Acoustic output is in conformity with the requirement of IEC 60061-2-37:2015 and IEC 62359: 2017.

Leakage current , patient auxiliary current and Dielectric strength

Leakage current , patient auxiliary current and Dielectric strength is in conformity with the requirement of IEC 60601-1:2020.

Biocompatibility

Biocompatibility of Disposable Sterile Endoscopic Ultrasonic Probe was evaluated in accordance with ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" .The following tests were performed, as recommended:

- Cytotoxicity
- Sensitization
- Intradermal reactivity

Software verification and Cybersecurity Test

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".

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 60601-1-2:2020 standards for EMC and IEC 60601-2-37:2015.

Performance testing - Animal

No animal study was performed to demonstrate substantial equivalence.

Performance testing - Clinical

No clinical study was performed to demonstrate substantial equivalence.

9. Conclusion

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.