May 14, 2026

Mytech Intelligence (Shenzhen) Co., Ltd.
℅ Amos Zou
Regulatory Director
Dongguan Woer Biotechnology Consulting Co., Ltd.
Room 802, Building 37, Sunshine Guangdong Garden
No. 72, Hengli Zhongshan East Road, Hengli Town
Dongguan, 523000
China

Re: K260111
Trade/Device Name: Palmtop Ultrasound Diagnostic System (MT10P/MT10)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: April 9, 2026
Received: April 9, 2026

Dear Amos Zou:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

Digitally signed by Michael D. O'hara -S
Date: 2026.05.14 17:26:45 -04'00' 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260111

Please provide the device trade name(s).

Palmtop Ultrasound Diagnostic System (MT10P/MT10)

Please provide your Indications for Use below.

The Palmtop Ultrasound Diagnostic System (Probe Model: C3-5) is intended for diagnostic ultrasound echo imaging measurement, and analysis of the human body for general clinical applications including obstetrics(OB), gynecology (GY) and general(abdominal) imaging.
The Palmtop Ultrasound Diagnostic System (Probe Model: L7-10) is intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including small organ and peripheral vessel imaging.

Mode of operation:
- Model B scan
- Model B/M scan
- Doppler(Color)
- Pulse Doppler(PW)

Operator qualifications: The operator should be capable to understand the Instructions for Use; The operator must be a trained professional doctor.

Device use settings: hospital.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use (21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

--K260111

1. 510(k) Submitter

- **Sponsor：**

Company Name:	Mytech Intelligence (Shenzhen) Co.,Ltd.
Address:	Room 605, 606, 615 & 616, Block R3-B, High-tech industrial village, No. 018, South 7th Gaoxin Road, Gaoxin Community, Yuehai Street, Nanshan District, Shenzhen,518100,China
Contact person:	Xulei Shi
TEL:	Engineer
E-mail:	will.shi@myetch-group.com

- **Application Correspondent:**

Company Name:	Dongguan Woer Biotechnology Consulting Co., Ltd.
Address:	Room 802, Building 37, No. 72 Zhongshan East Road, Hengli Town, Dongguan,Guangdong,523000,China
Contact person:	Mr. Amos Zou
TEL:	+86-15015249549
E-mail:	546977693@qq.com

Date 510(k) Summary Prepared: March 19, 2026

2 Proposed Device and code:

Trade Name of Device:	Palmtop Ultrasound Diagnostic System(MT10P / MT10)
Common Name:	21 CFR 892.1550
Regulation Name:	Ultrasonic pulsed doppler imaging system
Regulatory Class:	II
Product code:	IYN, IYO, ITX
Review Panel:	Radiology

3 **Predicate Device:**

510(K)	Trade or Proprietary or Model Name	Manufacturer

K211321	Wireless Probe Type Ultrasound Scanner (Model: CProbe; Type: Type C,Type L, Type CT, Type CL	Guangzhou Sonostar Technologies Co., Ltd.
K172750	Wireless Probe Type Ultrasound Scanner (Model: UProbe-C; UProbe-L; BProbe)	Guangzhou Sonostar Technologies Co., Ltd.

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

4. Device Description

The Palmtop Ultrasound Diagnostic System consists of a probe, control button, and host unit. Probe types include convex array and linear array. The product line includes two models: MT10P (with ultrasound teaching atlas) and MT10 (without ultrasound teaching atlas).

Operating modes of the Palmtop Ultrasound Diagnostic System include B-mode, B/M-mode, Color Doppler, Pulsed Doppler (PW),.

The Palmtop Ultrasound Diagnostic System is a wireless ultrasound system that uses pulsed-echo technology to transmit ultrasound images via wireless communication to a mobile device running iOS or Android operating systems.

Mobile devices compatible with the Palmtop Ultrasound Diagnostic System include those running iOS or Android, i.e., Apple iPad or iPhone devices and Android tablets or phones equipped with Snapdragon 660 (or equivalent or higher performance).

The Palmtop Ultrasound Diagnostic System is a portable, general-purpose, software-controlled, hand-held diagnostic ultrasound system composed of:

(1) a commercial off-the-shelf iOS or Android mobile device;

(2) the Wireless Probe Type Ultrasound Scanner application running on the mobile device;

(3) the battery-operated, hand-held Wireless Probe Type Ultrasound Scanner transducer that communicates wirelessly with iOS or Android mobile devices; and

(4) the instructions for use manual.

Device components are not supplied as sterile and do not require sterilization prior to use.

5 Indications for Use

The Palmtop Ultrasound Diagnostic System (Probe Model: C3-5) is intended for diagnostic ultrasound echo imaging measurement, and analysis of the human body for general clinical applications including obstetrics(OB), gynecology (GY) and general(abdominal) imaging.

The Palmtop Ultrasound Diagnostic System (Probe Model: L7-10) is intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including small organ and peripheral vessel imaging.

Mode of operation:

- Model B scan
- Model B/M scan
- Doppler(Color)
- Pulse Doppler(PW)

Operator qualifications: The operator should be capable to understand the Instructions for Use; The operator must be a trained professional doctor.

Device use settings: hospital.

6 Comparison of Technological Characteristics with the Predicate Device

6.1 Predicate Device 1 (Primary)

Comparison Item	**Predicate Device**	**Subject Device**
Classification & Intended Use		
510(k) No.:	K211321	K260111
Company	Guangzhou Sonostar Technologies Co., Ltd.	Mytech Intelligence (Shenzhen) Co.,Ltd.
Predicate Device:	Wireless Probe Type Ultrasound Scanner (Model: C Probe)	Palmtop Ultrasound Diagnostic System (MT10P / MT10)
Classification	Class II	Class II
Product Code	IYN, IYO, ITX	IYN, IYO, ITX
Intended Use	Intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including obstetrics (OB), gynecology (GY), and general (abdominal) imaging.	Intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including obstetrics (OB), gynecology (GY), and general (abdominal) imaging.
Technological Characteristics		
Environment of Use	Hospital, clinic, and medical office settings	Hospital

Acoustic Output Levels	Below FDA Track 3 limits in accordance with the September 2008 Ultrasound Systems Guidance	Below FDA Track 3 limits in accordance with the September 2008 Ultrasound Systems Guidance
Imaging Capabilities	- B-mode - BM-mode - Color Doppler - Pulsed Doppler (PW)	- B-mode - B/M-mode - Color Doppler - Pulsed Doppler (PW)
Patient Population	For use in all patients	For use in all patients
Principle of Operation	Piezoelectric material in the transducer transmits ultrasound waves into the body. Reflected waves are received by the transducer and converted into electrical signals, which are processed and displayed as anatomical images.	Piezoelectric material in the transducer transmits ultrasound waves into the body. Reflected waves are received by the transducer and converted into electrical signals, which are processed and displayed as anatomical images.
Image Display Unit	Mobile device (approximately 4–13 inches)	Mobile device (approximately 4–13 inches)
Probe Characteristics	Convex array, 3.5 MHz	Convex array, 3.5 MHz
Probe Connection	Wireless	Wireless
Operating System	iOS / Android	iOS / Android
Software	Runs as an application on off-the-shelf mobile devices	Runs as an application on off-the-shelf mobile devices
System Components	Commercial off-the-shelf iOS mobile device; ultrasound application software; battery-operated hand-held wireless transducer	Commercial off-the-shelf iOS/Android mobile device; ultrasound application software; battery-operated hand-held wireless transducer
Safety & Performance		
Biocompatibility	Evaluated per FDA-recognized standards ISO 10993-5 and ISO 10993-10	Evaluated per FDA-recognized standards ISO 10993-5 and ISO 10993-10

Electrical Safety	Evaluated per IEC 60601-1	Evaluated per IEC 60601-1
EMC	Evaluated per IEC 60601-1-2	Evaluated per IEC 60601-1-2
Ultrasound Safety	Evaluated per IEC 60601-2-37	Evaluated per IEC 60601-2-37

Brief Summary

The subject device (Model C Probe) has identical classification and indications for use as the predicate device, forming the basis for substantial equivalence.

The subject device has nearly identical technological characteristics to the predicate device. Differences are limited to imaging capabilities and environment of use. These differences do not affect the core function or safety profile, and the intended use environment of the subject device is fully encompassed by that of the predicate device. These facts further support that the devices are substantially equivalent.

The safety and effectiveness of the subject device have been evaluated against the same FDA-recognized standards as the predicate device, ensuring the subject device is as safe and effective as the predicate device.

Therefore, it is concluded that the subject device (Model C Probe) is **substantially equivalent** to the predicate device.

6.2 Predicate device 2 (Secondary)

Comparison for Probe Model L

Comparison Item	**Predicate Device**	**Subject Device**
Classification & Intended Use		
510(k) No.:	K172750	K260111
Company	Guangzhou Sonostar Technologies Co., Ltd.	Mytech Intelligence (Shenzhen) Co.,Ltd.
Predicate Device:	Palmtop Ultrasound Diagnostic System	Palmtop Ultrasound Diagnostic System (MT10P / MT10)
Classification	Class II	Class II
Product Code	IYN, IYO, ITX	IYO, ITX
Intended Use	Intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including small organ and peripheral vessel	Intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including small organ and peripheral vessel

	imaging.	imaging.
Technological Characteristics		
Environment of Use	Hospital	Hospital, clinic, medical office settings
Acoustic Output	Below FDA Track 3 limits (Sept 2008 guidance)	Below FDA Track 3 limits (Sept 2008 guidance)
Imaging Capabilities	B-mode, B/M-mode, Color Doppler, Pulsed Doppler (PW)	B-mode, B/M-mode
Patient Population	All patients	All patients
Operating Principle	Pulsed-echo ultrasound; piezoelectric transducer; wireless transmission to mobile display	Pulsed-echo ultrasound; piezoelectric transducer; wireless transmission to mobile display
Display	Mobile device (4–13 inches)	Mobile device (4–13 inches)
Probe Type	Linear array, 5 MHz	Linear array, 5 MHz
Communication	Wireless	Wireless
Operating System	iOS, Android	iOS
Software	Application-based on off-the-shelf mobile devices	Application-based on off-the-shelf mobile devices
Safety & Performance		
Biocompatibility	ISO 10993-5, ISO 10993-10	ISO 10993-5, ISO 10993-10
Electrical Safety	IEC 60601-1	IEC 60601-1
EMC	IEC 60601-1-2	IEC 60601-1-2
Ultrasound Safety	IEC 60601-2-37	IEC 60601-2-37

Brief Summary

The subject device (Model L Probe) has identical indications for use to the predicate device. Classification is consistent, and product codes are aligned, forming the basis for substantial equivalence.

Technological characteristics are nearly identical. Differences are limited to imaging capabilities,

environment of use, and operating system support. The addition of Android support expands compatibility but does not alter safety or effectiveness. The intended use environment of the subject device is fully encompassed by that of the predicate device. These facts further support substantial equivalence.

The subject device is demonstrated to be substantially equivalent to the legally marketed predicate device, and is safe and effective for its intended use.

Therefore, it is concluded that the subject device (Model L Probe) is **substantially equivalent** to the predicate device.

6.3 Clinical Test

Clinical testing was not performed for the Palmtop Ultrasound Diagnostic System as part of this 510(k) submission.

6.4 Non-Clinical Tests

Non-clinical testing and analysis were performed per the following standards to assure safety and performance:

- - Electrical Safety: IEC 60601-1:2005 + AMD1:2012 + AMD2:2020 (Medical electrical equipment – Part 1: General requirements for basic safety and essential performance)
- - Electromagnetic Compatibility: IEC 60601-1-2:2014 + A1:2020; EN 60601-1-2:2015 + A1:2021
- - Ultrasound Safety & Performance: IEC 60601-2-37 (2nd edition, 2007)
- - FCC RF Testing: FCC 47 CFR Part 15 Subpart C §15.247 (frequency hopping, direct sequence spread spectrum, and hybrid systems in 902–928 MHz, 2400–2483.5 MHz, and 5725–5850 MHz bands)

7 Conclusion

Based on the above comparisons and testing, it is concluded that the Palmtop Ultrasound Diagnostic System (MT10P / MT10) is as safe and effective as the legally marketed predicate devices cleared by the FDA.