October 13, 2022

Guangzhou Sonostar Technologies Co., Ltd.
℅ Weizhong Cai
General Manager
504#, C Building,#27 Yayingshi Road, Science Town
Guangzhou, Guangdong 510665
CHINA

Re: K211321
Trade/Device Name: Wireless Probe Type Ultrasound Scanner (Model: CProbe; Type: Type C, Type L, Type CT, Type CL
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: September 9, 2022
Received: September 9, 2022

Dear Weizhong Cai:

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,

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT 8C: 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)*
K211321

Device Name
Wireless Probe Type Ultrasound Scanner (Model: CProbe; Type: Type C, Type L, Type CT, Type CL)

Indications for Use *(Describe)*
The Wireless Probe Type Ultrasound Scanner (Model: CProbe; Type: Type C, Type L, Type CT, Type CL) 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 part of this device that is intended to contact with the patient is the probe head.

Modes of operation:
• Pulsed-echo ultrasound
• Mode B (2D) scan
• Mode BM scan
• Doppler mode (COLOR)
• Energy Doppler mode (PDI)
• Pulse Doppler (PW)

Operator qualifications: The operator should be capable to understand the Instructions for Use; The operator must be an appropriately-trained healthcare professional or used under the supervision of the authority of a physician.

Device use settings: hospital or home use.

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.

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007_510(k) Summary

(As required by 21 CFR 807.92(a))

K211321

7.1 Submitter Information

- Company: Guangzhou Sonostar Technologies Co., Ltd.
- Address: 504#, C Building, #27 Yayingshi Road, Science Town, Guangzhou, Guangdong, 510665, P.R.China
- Phone: 086-20-32382095
- Fax: 086-20-62614030
- Contact: Weizhong Cai, General Manager
- Date: Oct. 01, 2020

7.2 Device Information

- Trade/Device Name: Wireless Probe Type Ultrasound Scanner
  (Model: CProbe; Type: Type C, Type L, Type CT, Type CL)
- Common Name: Diagnostic Ultrasound System and Transducer
- Classification:

1) Device: System, Imaging, Pulsed Echo, Ultrasonic Regulation
Description: Ultrasonic pulsed echo imaging system

- Review Panel: Radiology
- Product Code: IYN, IYO
- Regulation Number: 21 CFR 892.1550
  21 CFR 892.1560
- Primary product code: IYN (associated regulation: 21 CFR 892.1550)
- Device Class: 2

2) Device: Transducer, Ultrasonic, Diagnostic

Regulation Description: Diagnostic ultrasonic transducer

Review Panel: Radiology

Product Code: ITX

Regulation Number: 21 CFR 892.1570

Device Class: 2

7.3 Predicate Device Information

Primary predicate device:

Wireless Probe Type Ultrasound Scanner (Model: UProbe-C; UProbe-L; BProbe) submitted by Guangzhou Sonostar Technologies Co., Ltd.

510K Number: K172750

Reference Device:

Vscan Air

submitted by GE VINGMED ULTRASOUND AS

(9900 Innovation Drive, wauwatosa, WI 53226)

510K Number: K202035

7.4 Device Description

The Wireless Probe Type Ultrasound Scanner (Model: CProbe; Type: Type C, Type L, Type CT, Type CL) is a wirelessultrasound system that uses pulsed-echo technology to transmit ultrasound images via wireless communication to a mobile device that utilizes the iOS operating system.

The mobile device for use with the Wireless Probe Type Ultrasound Scanner (Model: CProbe; Type: Type C, Type L, Type CT, Type CL) are those that utilizes the iOS operating system, i.e. all series of iPad or iPhone from Apple Inc.

The Wireless Probe Type Ultrasound Scanner is a portable, general-purpose, software-controlled, hand-held diagnostic ultrasound system that consists of (i) a commercial off-the-shelf iOS mobile device, (ii) the Wireless Probe

Type Ultrasound Scanner software that runs as an app on the mobile device, (iii) the battery-operated, hand-held Wireless Probe Type Ultrasound Scanner transducer that communicates wirelessly with iOS mobile devices, and (iv) the instructions for use manual, USB Cable for Charging.

The Wireless Probe Type Ultrasound Scanner utilizes pulsed-echo technology to determine the depth and location of tissue interfaces, and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver. Ultrasound waves are emitted from the transducer, propagate through tissues, and return to the transducer as reflected echoes. The returned echoes are then converted into electrical impulses by transducer crystals and further processed in order to form the ultrasound image presented on the screen.

The device components are not supplied sterile and do not require sterilization prior to use.

7.5 Indications for Use

The Wireless Probe Type Ultrasound Scanner (Model: CProbe; Type: Type C, Type L, Type CT, Type CL) 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 part of this device that is intended to contact with the patient is the probe head.

Modes of operation:

- Pulsed-echo ultrasound
- Mode B (2D) scan
- Mode BM scan
- Doppler mode (COLOR)
- Energy Doppler mode (PDI)

• Pulse Doppler (PW)

Operator qualifications: The operator should be capable to understand the Instructions for Use; The operator must be an appropriately-trained healthcare professional or used under the supervision of the authority of a physician.

Device use settings: hospital or home use.

7.6 Comparison of Technological Characteristics with the Predicate Device

7.6.1 Comparison Table of Technological Characteristic with the Predicate Device and Reference device for Model: CProbe

Comparison Items	Subject Device: Wireless Probe Type Ultrasound Scanner (Model: CProbe; Type: Type C, Type L, Type CT, Type CL)	Primary predicate device: Wireless Probe Type Ultrasound Scanner (Model: UProbe-C) (K172750)	Reference Device: Vscan Air (K202035)
Classification & Intended Use			
Classification	ITX & IYN & IYO Class 2	IYO & ITX Class 2	ITX & IYO & IYN Class 2

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.	The device is enabling visualization and measurement of anatomical structures and fluid including blood flow.

Technological Characteristics			
Environment of Use	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Professional healthcare facilities (ex. Hospital, clinic, medical office), home environment, road/air ambulance and other environments
Acoustic Output Levels	Below Track 3 FDA limits in accordance with Sept. 2008 ultrasound systems guidance document	Below Track 3 FDA limits in accordance with Sept. 2008 ultrasound systems guidance document	Below Track 3 FDA limits in accordance with Sept. 2008 ultrasound systems guidance document
Imaging Capacities	• Pulsed-echo ultrasound • Mode B (2D) scan • Mode BM scan • Doppler mode (COLOR) • Energy Doppler mode (PDI) • Pulse Doppler (PW)	• Pulsed-echo ultrasound • Mode B (2D) scan • Mode BM scan	• Black/ white (B-mode) • Harmonic imaging modes (PDI) • Combined (B + Color Doppler / PW mode) • Color flow (Color doppler),
Feature function	• Biopsy guideline • Harmonic function	• Biopsy guideline • Harmonic function	• Biopsy guideline • Harmonic function

Patient Population	For use in all patients	For use in all patients	For use in all patients
Principle /Mode of Operation	Piezoelectric material in the transducer is used as an ultrasound sourceto transmit soundwaves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as images of anatomic structures.	Piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as images of anatomic structures.	Medical ultrasound images are created by computer and digital memory from the transmission and reception of mechanical high-frequency waves applied through a probe. The mechanical ultrasound waves spread through the body, producing an echo where density changes occur. The echoes return to the probe where they are converted back into electrical signals. These echo signals are amplified and processed by several analog and digital circuits having filters with many frequency and time response options, transforming the high-frequency electrical signals into a series of digital image signals which are stored in memory. Once in memory, the image can be displayed in real-time on the display device.

Image Display Unit	Mobile device (4 to 13 inches approximately)	Mobile device (4 to 10 inches approximately)	Mobile device
Probe Characteristics	Convex, 3.5 MHz frequency;	Convex, 3.5 MHz frequency	Convex, 3.3MHz frequency
Probe Connectionto Display	Wireless	Wireless	Wireless
Off-the-shelf operating system	iOS / Android	iOS / Android	iOS / Android
Software	Run as an app on off-the- shelf mobile device	Run as an app on off-the- shelf mobile device	Run as an app on off-the- shelf mobile device
System Components	• Commercial • off-the-shelf iOS mobile device, • Wireless Probe Type Ultrasound Scanner software that runs as an app on the mobile device, • Wireless Probe Type Ultrasound Scanner battery-operated, hand-held ultrasound diagnostic transducer that communicates wirelessly with iOS or Android mobile devices	• Commercial off-the-shelf iOS mobile device, • Wireless Probe Type Ultrasound Scanner software that runs as an app on the mobile device, • Wireless Probe Type Ultrasound Scanner battery-operated, hand-held ultrasound diagnostic transducer that communicates wirelessly with iOS or Android mobile devices	• Mainframe • Software • Cable charger

Safety & Effectiveness			
Patient- Contacting Materials	Evaluated according to FDA recognized standards – ISO 10993-5 and ISO 10993-10	Evaluated according to FDA recognized standards – ISO 10993-5 and ISO 10993-10	Evaluated according to FDA recognized standards – ISO 10993-5 and ISO 10993-10
Electrical Safety	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1	Evaluated according to IEC 60601-1
EMC	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2	Evaluated according to IEC 60601-1-2
Performance Safety	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37	Evaluated according to IEC 60601-2-37

Brief Summary

First, the subject device (Model: CProbe) enjoys identical classification and intended use with the Primary predicate device and Reference device, which forms the foundation of their substantial equivalence.

Secondly, the subject device (Model: CProbe) boasts almost the same technological characteristics with the Primary predicate device. And their slight differences in imaging capacities, image display unit will not affect the coreusage of the two devices, thus will not affecting the substantial equivalence comparison between the two devices that the difference technological characteristics with the Reference Device on imaging capacities is covered. Such fact further supports that the two devices are substantial equivalent.

Last but not least, the safety and effectiveness of the subject device (Model: CProbe) have been evaluated according to the same FDA recognized standards as the Primary predicate device and Reference Device, which ensures that the subject device will be safe and effective for usage as the predicate device, that the two devices are substantial equivalent.

As a result, it is reasonable to conclude that subject device (Model: CProbe) is substantial equivalent with Primary predicate device.

7.6.2 Clinical Test

Clinical testing was not performed for Wireless Probe Type Ultrasound Scanner (Model: CProbe; Type: Type C, Type L, Type CT, Type CL) as part of the submission.

7.6.3 Non-Clinical Tests

The subject device was tested/analyzed according to the following standards in order to ensure its effectiveness and safety:

1) Biocompatibility according to AAMI / ANSI / ISO 10993-5:2009/(R)2014, Biological Evaluation Of Medical Devices - Part 5:Tests For In Vitro Cytotoxicity. (Biocompatibility) and AAMI / ANSI / ISO10993-10:2010/(R)2014, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization. (Biocompatibility);

2) Electrical Safety according to AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012,, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (Iec 60601-1:2005, Mod). (General II (ES/EMC));

3) Electromagnetic Compatibility according to AAMI / ANSI / IEC 60601-1-2:2007/(R)2012, Medical Electrical Equipment - Part 1-2: GeneralRequirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests (Edition3). (General II (ES/EMC));
4) Performance Safety and Effectiveness according to IEC 60601-2-37 Edition 2.0 2007, Medical Electrical Equipment - Part 2-37: Particular Requirements For The Basic Safety And Essential Performance Of Ultrasonic Medical Diagnostic And Monitoring Equipment. (Radiology);

5) FCC Radio Frequency Testing: The Wireless Probe Type Ultrasound Scanner was tested according to FCC requirements and found to comply with the requirements of FCC CFR Title 47 Part 15 Subpart C Section 15.247: Frequency Hopping, Direct Spread Spectrum and Hybrid Systems that are in operation with the bands of 902-928 MHz, 2400-2483.5 MHz, and 5725-5850 MHz.

7.7 Conclusion

From the above analysis, it is proper to conclude that the subject device (Model: CProbe) will be as safe and effective for usage as the listed predicate devices that have already been on the U.S. market.