DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Healcerion Co., Ltd.
% Ms. Carmelina G. Allis
The Allis Law Firm, PLLC
2437 Bay Area Blvd., #30
HOUSTON TX 77058

September 10, 2015

Re: K151339
Trade/Device Name: SONON Ultrasound Imaging System (Model: SONON 300C)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: August 10, 2015
Received: August 14, 2015

Dear Ms. Allis:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K151339

Device Name
SONON Ultrasound Imaging System (Model: SONON 300C)

Indications for Use *(Describe)*

The SONON Ultrasound Imaging System (Model: SONON 300C) 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Diagnostic Ultrasound Indications for Use Form

510(k) Number: K151339

Device Name: SONON Ultrasound Imaging System (Model: SONON 300C)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N						
	Abdominal	N						
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Genecology)	N						
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of In Vitro Diagnostics and Radiological Health

XX Prescription Use -- Yes

(Part 21 CFR 801 Subpart D)

K151339

510(k) Summary of Safety and Effectiveness

Healcerion Co., Ltd. SONON Ultrasound Imaging System, Model: SONON 300C

1) Submitter's name, address, telephone number; Contact person

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Date prepared: August 10, 2015

2) Name of the device, including the trade or proprietary name, if applicable, the common or usual name, and the classification name, if known

Device Common/Usual Name: Diagnostic Ultrasound System and Transducer

Device Proprietary Name: SONON Ultrasound Imaging System, Model: SONON 300C

Device Classification: Class II

21 C.F.R. Section	Classification Name	Product Code
892.1560	System, Imaging, Pulsed Echo, Ultrasonic	90-IYO
892.1570	Transducer, Ultrasonic, Diagnostic	90-ITX

3) Substantially Equivalent Devices

Device Name	510(k) Number
MobiUS Ultrasound Imaging System (Mobisante, Inc.)	K102153
Penrith Elettra Diagnostic Ultrasound System (Penrith Corp.)	K100598

Healcerion is not aware of any design-related recalls regarding the predicate devices. No reference devices were used in this submission.

4) Device Description

The SONON Ultrasound Imaging System, Model: SONON 300C, is a wireless ultrasound system that uses pulsed-echo technology (frequency: 3.5 MHz; module: convex) to transmit ultrasound images via wireless communication to a mobile device that utilizes the iOS or Android operating system.

The minimum requirements for the mobile devices that utilize the iOS or Android operating system for use with the SONON Ultrasound Imaging System, Model: SONON 300C are as follows:

Item	Minimum requirements
Target Device	iPhone 5 / 5S / 6 / 6 plus iPad 3rd / 4th Generation / Air / Mini or later Galaxy S3 / S4 / S5 / Note 3, Note 4 Galaxy Note Tablet 10.1 2013 version or later Galaxy Tab Pro 8.4 2014 version or later
Mobile OS Version	iOS 7.0 or later Android 4.3 or later

The SONON Ultrasound Imaging System is a portable, general-purpose, software-controlled, hand-held diagnostic ultrasound system that consists of (i) a commercial off-the-shelf iOS or Android mobile device, (ii) the SONON Ultrasound Imaging System software that runs as an app on the mobile device, (iii) the battery-operated, hand-held SONON Ultrasound Imaging System transducer that communicates wirelessly with iOS or Android mobile devices, and (iv) the instructions for use manual, battery, charger, and power cords.

The SONON software can be downloaded to an iOS or Android mobile device and utilizes an icon touch-based user interface. The software enables ultrasound image capture and review, controls for time gain, dynamic range, display of mirror image, focal length, depth, brightness, contrast, linear/elliptical measurement, and image annotation, as well as storage and email transmission of images and videos. The SONON Ultrasound Imaging System allows the user to image in real time and review cine or freeze-frame images on the screen in a B-Mode, 2-dimensional scan format. All images and data collected are stored in the mobile app. If the app is removed and reinstalled, all stored information is lost and cannot be recovered.

The SONON Ultrasound Imaging System 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.

5) Indications for Use

The SONON Ultrasound Imaging System (Model: SONON 300C) 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.

6) Technological Comparison to Predicate Devices

The SONON Ultrasound Imaging System and its predicate devices, the MobiUS and Penrith Elettra, are Track 3 systems that employ the same basic scientific technology for the acquisition and display of ultrasound images. They all operate in the same manner in that piezoelectric material in the transducer is used as a 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 2-dimensional images. The SONON Ultrasound Imaging System and the predicate devices allow for the visualization and measurement of body structures. All devices are intended to be used in clinical environments, including hospitals, clinics, and medical office settings, for the diagnosis of patients.

All devices are compact, portable, general-purpose, software-controlled diagnostic ultrasound imaging systems with hand-held probes. Both the SONON Ultrasound Imaging System and the Penrith Elettra devices utilize wireless network connectivity to run software and display images. Both the MobiUS and the SONON Ultrasound Imaging System are available in a 3.5 MHz ultrasound probe.

The patient-contacting surfaces of the subject and predicate devices have been found to be biocompatible for their intended application. The SONON Ultrasound Imaging System is manufactured and designed to the same electrical and safety standards as the predicate devices.

The SONON Ultrasound Imaging System display ranges from 4 to 10 inches depending on whether a mobile phone or tablet is used. This is similar to the range of display options available for the MobiUS and Penrith Elettra predicate devices.

Comparison of Technological Characteristics with Predicate Devices

Characteristic	**Healcerion Co., Ltd.** **SONON Ultrasound Imaging System**	**Predicate Device** **Mobisante, Inc.** **MobiUS Ultrasound Imaging System** **K102153**	**Predicate Device** **Penrith Corporation** **Penrith Elettra Diagnostic Ultrasound System** **K100598**
Intended Use/Indications for Use	The SONON Ultrasound Imaging System (Model: SONON 300C) is intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications	Indicated for ultrasound imaging, measurement, and analysis of the human body for the following clinical applications: fetal/OB, abdominal, cardiac, pelvic, pediatric, musculoskeletal, and peripheral vessel	Intended for diagnostic imaging or fluid flow analysis of the human body including: fetal, abdominal, intraoperative, intraoperative neurological, pediatric, small organ, neonatal

Characteristic	Healcerion Co., Ltd. SONON Ultrasound Imaging System	Predicate Device Mobisante, Inc. MobiUS Ultrasound Imaging System K102153	Predicate Device Penrith Corporation Penrith Elettra Diagnostic Ultrasound System K100598
	including obstetrics (OB), gynecology (GY) and general (abdominal) imaging.	imaging. Its compact size, portability, and user interface enable it for use in primary care and special care areas.	cephalic, cardiac, peripheral vessel, musculoskeletal (conventional), musculoskeletal (superficial).
Environment of Use	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings
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 Capabilities	• pulsed-echo ultrasound • Mode B (2D) scan	• pulsed-echo ultrasound • Mode B (2D) scan	• pulsed-echo and Doppler ultrasound • Mode B (2D), Color, Amplitude Doppler
Patient Population	For use in all patients	For use in all patients	For use in all patients
Anatomic Structures/Clinical applications	General clinical applications, including fetal/obstetrics, gynecology, abdominal	General clinical applications, including, but not limited to fetal/obstetrics, gynecology, abdominal, cardiac, pelvic, pediatric, musculoskeletal, and peripheral vessel imaging	General clinical applications, including fetal, abdominal, intraoperative, pediatric, small organ, cephalic, cardiac, peripheral vessel, and musculoskeletal
Users	Healthcare professionals	Healthcare professionals	Healthcare professionals
Principle/Method of Operation	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.	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.	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.
Image Display Unit	Mobile device (4 to 10 inches approximately)	PC/Host computer (4.1 inches approximately)	Video display (unknown size)
Probe Characteristics	Convex, 3.5 MHz frequency	Mechanic, 3.5 MHz to 12 MHz frequency	L8-3 linear, L12-5 linear, and C5-2 curvilinear
Probe Connection to Display	Wireless	Wired (USB)	Wireless or wired
Off-the-shelf operating system	iOS / Android	Win CE	Unknown
Software	Runs as an app on off-the-shelf mobile device	Runs in host computer	Unknown
System Components	• Commercial off-the-shelf iOS or Android mobile device, • SONON Ultrasound Imaging System software that runs as an app on the mobile device, • SONON Ultrasound Imaging System battery-operated, hand-held ultrasound diagnostic transducer that communicates wirelessly with	• Host computer, • USB 2.0 interface, and • Portable, handheld, compact ultrasound probe	• System console housing electronic circuitry • Video display • Power supply • User controls • Transducers (L8-3 linear, L12-5 linear, C5-2 curvilinear) that communicate wirelessly or via wire with system console

Characteristic	Healcerion Co., Ltd. SONON Ultrasound Imaging System	Predicate Device Mobisante, Inc. MobiUS Ultrasound Imaging System K102153	Predicate Device Penrith Corporation Penrith Elettra Diagnostic Ultrasound System K100598
	iOS or Android mobile devices		
Patient-Contacting Materials	All materials with patient contact are biocompatible and can be disinfected	All materials with patient contact are biocompatible and can be disinfected	All materials with patient contact are biocompatible

7) Determination of Substantial Equivalence

The SONON Ultrasound Imaging System is substantially equivalent to the predicate devices identified above with respect to intended use, principles of operation, and technological characteristics. As described below, the system has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness, and thermal, electrical, and mechanical safety, and has been found to conform to applicable standards and product specifications that demonstrate that the SONON Ultrasound Imaging System is substantially equivalent to the predicate devices.

Non-clinical performance data

Non-clinical tests relied on this premarket notification submission for a determination of substantial equivalence include testing showing compliance with the following standards.

Electrical safety, EMC, and RF Wireless Capabilities

Electrical safety, electromagnetic compatibility, and RF wireless capabilities were evaluated per international standards and the device complies with the following standards:

- IEC 60601-1: Medical Electrical Equipment - General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60601-2-37: Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 62359: Ultrasonics – Field Characterization – Test Methods for the Determination of Thermal and Mechanical Indices Related to Medical Diagnostic Ultrasonic Fields

Acoustic Output Levels

The acoustic output exposure levels were measured and calculated following the NEMA UD2-2004 (R2009), Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3. Acoustic Output Level Test Results are as follows:

Transducer	Ispta.3	TIS	MI	Ipa.3@MI_{max}
Convex only	0.0627[W/cm^2]	0.2535	0.7861	11.6369[W/cm^2]

Clinical Measurement Range and Accuracies

Clinical Measurement Range and Accuracies were tested using a phantom with vertical, dead zone, horizontal and linear groups. The length and the vertical and horizontal resolutions were evaluated and results met performance criteria.

Display Performance Testing

The SONON Ultrasound Imaging System (Model: SONON 300C) displays ranges from 4 to 10 inches depending on whether a mobile phone or tablet is used. This is similar to the range of display options available for the predicate devices. The display performance of the device was assessed using various mobile devices, and the test results demonstrate that the device meets performance specifications.

Usability Report

The usability engineering process was conducted by Healcerion to assess and mitigate risks caused by usability problems associated with the correct use of the device as well as user errors. The test results demonstrate that the product has been found to be reasonably safe and effective for the intended users, intended uses, and intended use environments through usability engineering process.

Failure Mode and Risk Analyses

Healcerion conducted a Failure Mode and Effects Analysis and a risk analysis in accordance with ISO 14971. The risk analysis of SONON 300C was performed by taking into account the risks of the device, such as design, production, storage, related international standards, state of art of risk management, and the foreseeable risks related to the intended use of the device. The hazards were identified, the risks were estimated, and procedures were implemented to control them. All identified hazards were reduced to acceptable levels.

Biocompatibility

Biocompatibility testing was conducted in accordance with the international standard below. The patient-contacting surfaces of the device (probe nosepiece and lens) were evaluated for cytotoxicity, skin irritation and skin sensitization. Test results demonstrate that the patient-contacting surfaces of the probe are biocompatible in accordance with the following standard:

- ISO 10993-1: Biological Evaluation of Medical Devices

Software Evaluation and Cybersecurity Management

Furthermore, Healcerion conducted validation and verification activities on the SONON Ultrasound Imaging System software. Cybersecurity evaluation was also conducted. The software passed its performance requirements and met specifications per the following standard:

- IEC 62304: Medical Device Software - Software Life-Cycle Processes

Additional Standards

Healcerion also relied on the following standards to ensure the substantial equivalence of the SONON Ultrasound Imaging System to predicate devices:

- ISO 14971: Application of Risk Management to Medical Devices
- ISO 15223-1: Symbols to be used with Medical Device Labels

Healcerion applied quality assurance measures to the system design and development, including, but not limited to:

- Risk Analysis
- Product Specifications
- Design Reviews
- Verification and Validation Activities

Clinical tests and animal studies - not conducted

The Healcerion SONON Ultrasound Imaging System ultrasound system does not introduce new indications for use, modes, features, or technologies relative to the predicate devices that would require evaluation through clinical or animal testing. The clinical safety and effectiveness of ultrasound systems with characteristics similar to those of the SONON 300C are well accepted for the predicate and subject devices.

8) Conclusion

In conclusion, the tests conducted, as well as all verification and validation activities, demonstrate that the design specifications and technological characteristics of the SONON Ultrasound Imaging System (Model: SONON 300C) meet applicable requirements and standards for the safety and effectiveness of the device for its intended use. There are some differences in technological characteristics between the predicate and proposed devices, but those differences only indicate that the predicate devices may have secondary or added functionalities as compared to the SONON Ultrasound Imaging System, such as additional probe models or imaging capabilities as in the case of Doppler ultrasound. The testing and validation activities conducted demonstrate that any differences between the devices do not raise new or different questions of safety or effectiveness as compared to the predicate devices. Therefore, the SONON Ultrasound Imaging System (Model: SONON 300C) is substantially equivalent to the predicate devices.