Healcerion Co., Ltd.
℅ Jong Hyun Kim
Senior Consultant
GMS Consulting Co., Ltd.
34, Sangamsan-ro, Mapo-gu
Seoul, 03909
REPUBLIC OF KOREA

May 16, 2022

Re: K211665
Trade/Device Name: SONON Ultrasound Imaging System, Model: SONON300C
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: April 18, 2022
Received: April 19, 2022

Dear Jong Hyun Kim:

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

801and Part 809); 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,

For

Michael D. O'Hara, Ph.D.
Deputy Director
DHT 8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT 8: 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)*

K211665

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. The system operating modes is B (Brightness), CF (color flow), PW (pulsed wave), M (motion). The intended to be used in a hospital or medical clinic is used by appropriately trained healthcare professionals, including radiologists, sonographers, technologists, and clinicians, in a medical 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.

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510(k) Summary

This summary of safety and effectiveness information is submitted in accordance with 21 CFR § 807.92.

1. Submitter

- Manufacturer : HEALCERION Co., Ltd.
- Address : 1403-ho, 12, Digital-ro 33-gil, Guro-gu, Seoul, 08377 Korea
- Telephone No. : +82-70-8217-0820
- E-mail Address : peter@healcerion.com
- Contact Information : LEE SOOYEOL / CTO
  Email : peter@healcerion.com

2. Device Name and Classification

- Device Common/Usual Name : Diagnostic Ultrasound System and Transducer
- Device Proprietary Name : SONON Ultrasound Imaging System, Model: SONON 300C
- Regulation Name : System, Imaging, Pulsed Doppler, Ultrasonic System, Imaging, Pulsed Echo, Ultrasonic Transducer, Ultrasonic, Diagnostic
- Device Classification : Class II
- Product Code : IYN, IYO, ITX
- Regulation Number : 21 C.F.R. § 892.1550, § 892.1560, and § 892.1570
- Classification Panel : Radiology

3. Predicate Device

The predicate devices of the subject device are as follows:

Predicate Device #1 (Primary Predicate Device)

- K Number : K151339
- Manufacturer : HEALCERION CO., LTD.
- Device Common/Usual Name : Diagnostic Ultrasound System and Transducer
- Device Proprietary Name : SONON Ultrasound Imaging System, Model: SONON 300C
- Regulation Name : System, Imaging, Pulsed Echo, Ultrasonic
- Device Classification : Class II
- Product Code : IYO, ITX
- Regulation Number : 21 C.F.R. § 892.1560, and § 892.1570
- Classification Panel : Radiology

Predicate Device #2 (Secondary Predicate Device)

- K Number : K192107
- Manufacturer : Clarius Mobile Health Corp.
- Device Common/Usual Name : Diagnostic Ultrasound System and Accessories
- Device Proprietary Name : Clarius Scanner C3 HD
- Regulation Name : System, Imaging, Pulsed Echo, Ultrasonic
- Device Classification : Class II
- Product Code : IYN, IYO, ITX
- Regulation Number : 21 C.F.R. § 892.1550, § 892.1560, and § 892.1570
- Classification Panel : Radiology

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

4. Reason for Submission

Following changes have been made compared to the cleared device (Predicate Device #1)

- Software (Mobile application) Changes: Windows 10 support, several features added (Supporting Server Login, Quick Scan, etc.)
- Cybersecurity Measures implemented

- Label Changes: Device label, Box label, User Manual
- Battery Cell and its nominal voltage changed
- Power Board changed to support additional modes (CF, PW, M Mode)
- Wi-Fi driver changed to support both 2.4 GHz & 5GHz connectivity
- A measuring mode added which is designed for assessing fetal biometry
- Available display depth range changed

5. 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, or PC that uses Windows operating system.

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

Operating system	Requirement	Compatible Devices
iOS	• iOS 11.0 or later	• iPhone 6S and newer • iPad 5 and newer • iPad Air 2 and newer • iPad Mini 4 and newer • iPad Pro and newer
Android	• Android 5.0 (Lollipop) or later	• Samsung Galaxy S6 and newer • Samsung Galaxy Note 5 and newer • Samsung Galaxy Tab S3 and newer
Windows (UWP)	• Windows 10 (64-bit) or later	• Microsoft Surface Pro 3 and newer

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, or Windows PC

(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, Android mobile device or Windows PC 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, color flow, and image annotation, as well as storage and PACS 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 and Color Flow Doppler (CF Mode) Mode with 2-dimensional scan format. In addition, PW (pulsed wave) mode displays different wave velocities and directions in a spectrum. Moreover, in M mode (also known as "motion mode"), the changes over time on a line graph appears in a spectrum.

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.

6. 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. The system operating modes is B (Brightness), CF (color flow), PW (pulsed wave), M (motion). The intended to be used in a hospital or medical clinic is used by appropriately trained healthcare professionals, including radiologists, sonographers, technologists, and clinicians, in a medical facility.

7. Technological Comparison to Predicate Devices

Table 1: Technological Comparison of Subject Device (i.e., SONON 300C and Predicate Device #1 (K151339))

Standard Feature	The SONON Ultrasound Imaging System, Model: SONON 300C K# Unknown (Subject Device)	The SONON Ultrasound Imaging System, Model: SONON 300C K151339 (Predicate Device #1)	Comparison
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. The system operating modes is B (Brightness), CF (color flow), PW (pulsed wave), M (motion). The intended to be used in a hospital or medical clinic is used by appropriately trained healthcare professionals, including radiologists, sonographers, technologists, and clinicians, in a medical facility.	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.	Identical
Environment of Use	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Identical
Acoustic Output Levels	Below Track 3 FDA limits in accordance with "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers", June. 2019	Below Track 3 FDA limits in accordance with "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers", June. 2019	Identical
Imaging Capabilities	• pulsed-echo, pulsed-doppler • Mode B (2D), Mode M (Motion), Mode CF (Color Flow), Mode PW (Pulsed Wave)	• pulsed-echo • Mode B (2D)	Different
Patient Population	For use in all patients	For use in all patients	Identical
Anatomic Structures/Clinical applications	general clinical applications including obstetrics (OB), gynecology (GY) and general (abdominal) imaging.	general clinical applications including obstetrics (OB), gynecology (GY) and general (abdominal) imaging.	Identical

Standard Feature		The SONON Ultrasound Imaging System, Model: SONON 300C K# Unknown (Subject Device)	The SONON Ultrasound Imaging System, Model: SONON 300C K151339 (Predicate Device #1)	Comparison
Users		appropriately trained healthcare professionals	healthcare professionals	Identical
Probe Characteristics		Convex, 3.5 MHz	Convex, 3.5 MHz	Identical
Probe Connection to Display		Wireless	Wireless	Identical
Software	Type	Mobile application operating on Off-the-shelf Operating Systems	Mobile application operating on Off-the-shelf Operating Systems	Identical
	Compatible OS	iOS / Android / Windows	iOS / Android	Different
Patient-Contacting Materials		All patient-contact materials are biocompatible and can be disinfected	All patient-contact materials are biocompatible and can be disinfected	Identical
Reusable?		Yes	Yes	Identical
Duration of Use		Limited (<24 hours)	Limited (<24 hours)	Identical

Table 2: Technological Comparison of Subject Device (i.e., SONON 300C and Predicate Device #2 (K192107))

Standard Feature	The SONON Ultrasound Imaging System, Model: SONON 300C K# Unknown (Subject Device)	Clarius Scanner C3 HD K192107 (Predicate Device #2)	Comparison
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. The system operating modes is B (Brightness), CF (color flow), PW (pulsed wave), M (motion). The intended to be used in a hospital or medical clinic is used by appropriately trained healthcare professionals, including radiologists, sonographers, technologists, and clinicians, in a medical facility.	Intended for diagnostic imaging. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: fetal, abdominal, intra-operative (non-neurological), pediatric, cephalic (adult), musculo-skeletal (conventional), urology, gynecology, cardiac (adult, pediatric), and peripheral vessel. The system is a transportable ultrasound system intended for use in environments where healthcare is provided by trained healthcare professionals.	Identical
Environment of Use	Hospital, clinic, and medical office settings	The system is a transportable ultrasound system intended for use in environments where healthcare is provided by trained healthcare professionals.	Identical
Acoustic Output Levels	Below Track 3 FDA limits in accordance with "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers", June. 2019	Below Track 3 FDA limits in accordance with "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers", June. 2019	Identical
Imaging Capabilities	• pulsed-echo, pulsed-doppler • Mode B (2D), Mode M (Motion), Mode CF (Color Flow), Mode PW (Pulsed Wave)	• pulsed-echo, pulsed-doppler • Mode B (2D), Mode M (Motion), Mode Color Doppler, Mode PW (Pulsed Wave), Mode Power Doppler	Identical
Patient Population	For use in all patients	For use in all patients	Identical

Standard Feature		The SONON Ultrasound Imaging System, Model: SONON 300C K# Unknown (Subject Device)	Clarius Scanner C3 HD K192107 (Predicate Device #2)	Comparison
Anatomic Structures/Clinical applications		general clinical applications including obstetrics (OB), gynecology (GY) and general (abdominal) imaging.	fetal, abdominal, intra-operative (non-neurological), pediatric, cephalic (adult), musculo-skeletal (conventional), urology, gynecology, cardiac (adult, pediatric), and peripheral vessel.	Identical
Users		appropriately trained healthcare professionals	Healthcare professionals.	Identical
Probe Characteristics		Convex, 3.5 MHz	Convex, 2~6 MHz	Different
Probe Connection to Display		Wireless	Wireless	Identical
Software	Type	Mobile application operating on Off-the-shelf Operating Systems	Mobile application operating on Off-the-shelf Operating Systems	Identical
	Compatible OS	iOS / Android / Windows	iOS / Android	Different
Patient-Contacting Materials		All patient-contact materials are biocompatible and can be disinfected	All patient-contact materials are biocompatible and can be disinfected	Identical
Reusable?		Yes	Yes	Identical
Duration of Use		Limited (<24 hours)	Limited (<24 hours)	Identical

8. Determination of Substantial Equivalence

The SONON Ultrasound Imaging System, Model: SONON 300C is substantially equivalent to the predicate devices identified above with respect to intended use, principles of operation, and technological characteristics. From the information provided in table above; it is understood that the subject device does not introduce any new technology and/or indications of use. Therefore, SONON 300C is considered substantially equivalent to the predicate devices

9. Summary of Design Control Activities and Performance Data

The SONON Ultrasound Imaging System, Model: SONON 300C is verified and validated according to the FDA design control requirements, 21 CFR 820. The subject device had been subjected to the applicable safety and performance testing before release to ensure the device meets all its specifications. The quality assurance measures applied to the design and development of the subject device include, but not limited to risk analysis, verification and validation, product specifications and design reviews.

A. Software

In accordance with the FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005, documentation is included within this submission for software of a Moderate Level of Concern. For all software changes in the device, software verification and validation activities have been conducted during product development including conformance to the following standards:

- IEC 62304:2006/AMD1:2015
- AAMI TIR 57:2016

Cybersecurity considerations to The SONON Ultrasound Imaging System software have been addressed in the submission. As per FDA's Guidance Document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" issued on Oct 2, 2014, Healcerion has implemented cybersecurity measures to prevent unauthorized access, modification, misuse, unauthorized use of information stored, etc.

Software and cybersecurity risk regarding software changes was identified, and the mitigation controls were implemented for identified risks. Software verification and validation testing confirm that all software specifications have been implemented on the previously cleared device and met the defined acceptance criteria.

B. Performance Testing - Bench

Design control activities were conducted for the changes which may affect the acoustic

output, clinical measurement range and accuracies, and Wi-Fi Connectivity.

The acoustic output exposure levels were measured, calculated, and derated following IEC 62359:2010/AMD1:2017. The test methodology for the measurement of acoustic output levels is exact same as a cleared device. Test result show that the acoustic output of modified device complies with the requirement for acoustic output level as per FDA Guidance "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers", issued on June 27, 2019.

To support substantial equivalence to the predicate devices, Healcerion conducted performance test related to clinical measurement range accuracies such as vertical/horizontal resolution, maximal viewing depth, vertical/horizontal distance accuracy, acoustic output frequency, etc. The device met the pre-defined acceptance criteria for the performance test, and its results show that the changes are acceptable in perspective of safety and effectiveness of the device.

For Wi-Fi connectivity that support both 2.4 GHz and 5 GHz, performance test was conducted to ensure that the change in Wi-Fi driver on the device performs equivalently to the predicate devices.

C. Biocompatibility

NO changes have been applied to the materials of the previously cleared device.

D. Cleaning and disinfection effectiveness

NO changes have been applied to the cleaning and disinfection method of the previously cleared device.

E. Thermal, electrical, mechanical safety & Electromagnetic Compatibility

Due to the modification in Power Board, Wi-Fi driver, and Battery Cell, the verification was conducted in compliance with well-established method as per IEC 60601-1:2005/AMD1:2012 and IEC 60601-2-37:2007/AMD1:2015 to confirm the device's thermal, electrical, and mechanical safety. Furthermore, the modified device was also tested as per IEC 60601-1-2:2014 and IEC 62133-2:2017 for these changes.

The result of safety and EMC test show that the changes are acceptable in perspective of the electromagnetic compatibility and electrical safety of the device.

F. Clinical tests and animal studies

NO clinical test nor animal study was performed to support substantial equivalence.

10. Conclusion

The conducted tests, as well as all verification and validation activities, demonstrate that the modified SONON Ultrasound Imaging System, Model: SONON 300C meet applicable requirements and standards for the safety and effectiveness of the device for its intended use. Additionally, any differences between the subject device and the predicate 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 in safety and effectiveness to the predicate devices.