April 22, 2022

Healcerion Co., Ltd.
℅ Jong Hyun Kim, Chief Consultant
GMS Consulting
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Seoul, Seoul 03909
REPUBLIC OF KOREA

Re: K212400
Trade/Device Name: SONON Ultrasound Imaging System, Model: SONON 500L
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: March 25, 2022
Received: March 25, 2022

Dear Jong 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

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 S. Kang -S For

Jessica Lamb, Ph.D.
Assistant Director
Division of Radiological Health
OHT7: Office of in vitro Diagnostics
and 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)*
K212400

Device Name
SONON Ultrasound Imaging System (Model: SONON 500L)

Indications for Use *(Describe)*
The SONON Ultrasound Imaging System (Model: SONON 500L) is intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including musculoskeletal (MSK), vascular, small parts (breast, thyroid), and thorax (thoracic/pleural motion and fluid detection imaging).

SONON 500L provides 4 modes: B (2D) mode, CF (Color Flow) mode, PW (Pulsed Wave) mode, M (Motion) mode.

SONON 500L is suitable for use in professional healthcare environment (hospital, clinic and medical office settings) by appropriately trained healthcare professional.

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 of Safety and Effectiveness

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

Date Prepared: March. 15. 2022

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
- Contact Information : Jeongwon Ryu / CEO
  Email: DrRyu@healcerion.com

2. Device Name and Classification

- K Number : K212400
- Device Common/Usual Name : Diagnostic Ultrasound System and Transducer
- Device Proprietary Name : SONON Ultrasound Imaging System, Model: SONON 500L
- Classification Name : Ultrasonic Pulsed Doppler Imaging System
  Ultrasonic Pulsed Echo Imaging System
  Diagnostic Ultrasonic Transducer
- Device Classification : Class II
- Product Code : IYN, IYO, ITX
- Regulation Number : 21 C.F.R. § 892.1550
  21 C.F.R. § 892.1560
  21 C.F.R. § 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 : K192107
- Manufacturer : Clarius Mobile Health Corp.

- Device Common/Usual Name : Diagnostic Ultrasound System and Accessories
- Device Proprietary Name : Clarius Scanner L7 HD
- Classification Name : Ultrasonic Pulsed Doppler Imaging System
- 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

Predicate Device #2 (Secondary predicate device)

- K Number : K170085
- Manufacturer : HEALCERION CO., LTD.
- Device Common/Usual Name : Diagnostic Ultrasound System and Transducer
- Device Proprietary Name : SONON Ultrasound Imaging System, Model: 300L
- Classification Name : Ultrasonic Pulsed Doppler Imaging System
- 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. Device Description

The SONON Ultrasound Imaging System, Model: SONON 500L, is a wireless ultrasound system that uses pulsed-echo / Doppler technology (Color Flow Doppler (CF Mode) / Brightness mode(2D B Mode) / Pulsed wave mode(PW Mode) / Motion mode(M mode); frequency: 4 MHz – 13MHz; module: linear; depth max: 6 cm) 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 500L are as follows:

-Operating system versions

Operating system	Requirement
iOS	iOS 11.0 or later
Android	Android 5.0 (Lollipop) or later
Windows (UWP)	Windows 10 (64-bit) or later

-Minimum specifications for mobile devices

Item	Requirement
CPU	1.7GHz
Core	8 cores
RAM	4GB
Resolution	2560 X 1600 (287ppi)

The SONON Ultrasound Imaging System is a **TRACK 3**, 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 or Windows PC and
(iv) the instructions for use manual, battery, charger, and power cords.

The mobile application of SONON 500L, which controls the probe, imaging capabilities and functionalities, 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, 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 with 2-dimensional scan format. The software also allows the user to save / edit patient and diagnosis information. An identification and password are required for accessing the SONON 500L app via the mobile device or PC. All information captured is saved in the app. If the app is removed and reinstalled, all stored information is lost and cannot be recovered.

The SONON ultrasound device utilizes pulsed-echo technology to determine the depth and location of tissue interfaces. Ultrasound imaging requires mechanical oscillation of crystals excited by electrical pulses, generating a piezoelectric effect. A number of these crystals make up a transducer, which converts one type of energy into another. Using pulse-echo transformation by the piezoelectric crystals, an ultrasound transducer converts electricity into sound.

The SONON ultrasound device measures the duration of an acoustic pulse travelling from the transmitter to the tissue interface and back to the receiver. Ultrasound waves emitted from the transducer propagate through various tissues and return to the transducer as reflected echoes. These echoes are then converted into high-frequency electrical signals by the crystals in the transducer. Next, the signals are amplified and further processed by several analog and digital circuits and software filters to adjust the frequency and time response, in order to finally generate a series of digital images.

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 500L) is intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including musculoskeletal (MSK), vascular, small parts (breast, thyroid), and thorax (thoracic/pleural motion and fluid detection imaging).

SONON 500L provides 4 modes: B (2D) mode, CF (Color Flow) mode, PW (Pulsed Wave) mode, M (Motion) mode.

SONON 500L is suitable for use in professional healthcare environment (hospital, clinic and medical office settings) by appropriately trained healthcare professional.

6. Technological Comparison to Predicate Devices

Table 1: Technological Comparison of Subject Device (i.e., SONON 500L and Predicate Device #1(K192107))

Standard Feature	The SONON Ultrasound Imaging System, Model: SONON 500L K# Unknown (Subject Device)	Clarius Scanner L7 HD K192107 (Predicate Device #1)	**Comparison**
Indications for Use	The SONON Ultrasound Imaging System (Model: SONON 500L) is intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including musculoskeletal (MSK), vascular, small parts (breast, thyroid), and thorax (thoracic/pleural motion and fluid detection imaging). SONON 500L provides 4 modes: B (2D) mode, CF (Color Flow) mode, PW (Pulsed Wave) mode, M (Motion) mode. SONON 500L is suitable for use in professional healthcare environment (hospital, clinic and medical office settings) by appropriately trained healthcare professional.	The Clarius Ultrasound Scanner is a software-based ultrasound imaging system and accessories, intended for diagnostic imaging. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: ophthalmic, fetal, abdominal, intra-operative (non-neurological), pediatric, small organ, cephalic (adult), trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), urology, gynecology, cardiac (adult, pediatric), peripheral vessel, carotid, and procedural guidance of needles into the body. The system is a transportable ultrasound system intended for use in environments where healthcare is provided by trained healthcare professionals.	The indications for use of the subject device are covered in those of predicate device except the clinical applications. The subject device's clinical applications are less than the predicate device. The subject device's applications include conventional/superficial musculo-skeletal, Peripheral vessel, and carotid in B, M, PWD, and Color Doppler mode, small organ (Thyroid, Breast) in B, PWD and Color Doppler mode, and thoracic/pleural motion and fluid detection in B Mode. Since these clinical applications are also supported in the predicate device, it is expected that the application mode in the subject device can well-operate as equivalently as the predicate device.
Environment of Use	Use in professional healthcare environment (hospital, clinic and medical office settings) by appropriately trained healthcare professional.	Place 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	Below Track 3 FDA limits in accordance with "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers",	Acoustic output of both devices is less than FDA established limits.

Standard Feature	The SONON Ultrasound Imaging System, Model: SONON 500L K# Unknown (Subject Device)	Clarius Scanner L7 HD K192107 (Predicate Device #1)	**Comparison**
	Transducers", June. 2019	June. 2019	
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	The available image modes of subject device are included in the predicate device mode (e.g., B, M, Pulsed Wave doppler, Color Flow doppler), and only the power doppler mode in the predicate device is not included in the subject device. In addition, such difference can be verified and validated via well-established method. In the performance aspects of the subject device, acoustic output levels were conducted. Likewise, the subject device was tested according to IEC 60601-1 and IEC 60601-2-37. Furthermore, utilized software in the subject device was also verified and validated.
Patient Population	For use in all patients	For use in all patients	Identical
Anatomic Structures/Clinical applications	Musculoskeletal (MSK), vascular, small parts (breast, thyroid), and thorax (thoracic/pleural motion and fluid detection imaging).	Ophthalmic, abdominal, intra-operative (non-neurological), pediatric, small organ, cephalic (adult), Musculo-skeletal (conventional, superficial), peripheral vessel, carotid, and procedural guidance of needles into the body.	The subject device's clinical applications are less than the predicate device. The subject device's applications include conventional/superficial musculo-skeletal, Peripheral vessel, and carotid in B, M, PWD, and Color Doppler mode, small organ (Thyroid, Breast) in B, PWD and Color Doppler mode, and thoracic/pleural motion and fluid detection in B Mode. Since these clinical applications are also supported in the predicate device, it is expected that the application mode in the subject device can well-operate as equivalently as the predicate device.

Standard Feature		The SONON Ultrasound Imaging System, Model: SONON 500L K# Unknown (Subject Device)	Clarius Scanner L7 HD K192107 (Predicate Device #1)	**Comparison**
Users		Healthcare professionals	Healthcare professionals	Identical
Probe Characteristics		Linear, 4~13 MHz	Linear, 4~13 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	The mobile application of the subject device can operate on iOS / Android / Windows operating system whereas the application of the predicate device only can operate on iOS and Android. However, all applications running on each operating system are compiled from the same source code and managed as one software. Therefore, there are no functional differences between the application running on Windows and others in the perspective of the device's safety and effectiveness.
Patient-Contacting Materials		All patient-contact materials are biocompatible and can be disinfected	All patient-contact materials are biocompatible	Both devices comply with ISO 10993-1 standards and the subject device can be disinfected by using approved cleaning products.
Reusable?		Yes	Yes	Identical
Duration of Use		Limited (<24 hours)	Limited (<24 hours)	Identical

Table 2: Technological Comparison of Subject Device (i.e., SONON 500L and Predicate Device #2 (K170085))

Standard Feature	The SONON Ultrasound Imaging System, Model: SONON 500L K# Unknown (Subject Device)	The SONON Ultrasound Imaging System, Model: SONON 300L K170085 (Predicate Device #2)	**Comparison**
Indications for Use	The SONON Ultrasound Imaging System (Model: SONON 500L) is intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including musculoskeletal (MSK), vascular, small parts (breast, thyroid), and thorax (thoracic/pleural motion and fluid detection imaging). SONON 500L provides 4 modes: B (2D) mode, CF (Color Flow) mode, PW (Pulsed Wave) mode, M (Motion) mode. SONON 500L is suitable for use in professional healthcare environment (hospital, clinic and medical office settings) by appropriately trained healthcare professional.	The SONON Ultrasound Imaging System (Model: 300L) is intended for diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including musculoskeletal (MSK), vascular, small parts (breast, thyroid), and thoracic/pleural motion and fluid detection imaging.	Everything is identical except the imaging capabilities.
Environment of Use	Use in professional healthcare environment (hospital, clinic and medical office settings) by appropriately trained healthcare professional.	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	The acoustic output of both devices is less than FDA established limits.

Standard Feature		The SONON Ultrasound Imaging System, Model: SONON 500L K# Unknown (Subject Device)	The SONON Ultrasound Imaging System, Model: SONON 300L K170085 (Predicate Device #2)	**Comparison**
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), color scan	The additional imaging modes are provided comparing to the predicate device (Mode B, CF, M, PW vs. Mode B, CF). However, such changes can be verified and validated via well-established method. In the performance aspects of the subject device with the additional modes, the test for acoustic output levels were conducted. Likewise, the subject device was tested according to IEC 60601-1 and IEC 60601-2-37. Furthermore, utilized software in the subject device was also verified and validated.
Patient Population		For use in all patients	For use in all patients	Identical
Anatomic Structures/Clinical applications		Musculoskeletal (MSK), vascular, small parts (breast, thyroid), and thorax (thoracic/pleural motion and fluid detection imaging).	Musculoskeletal (MSK), vascular, small parts (breast, thyroid), and thoracic/pleural motion and fluid detection imaging.	Identical
Users		Healthcare professionals	Healthcare professionals	Identical
Probe Characteristics		Linear, 4~13 MHz	Linear, 5 MHz / 7.5 MHz / 10 MHz	Such differences that may affect the device's safety and effectiveness can be compared and equivalent to the predicate device #1 (Clarius's L7 HD).
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	The mobile application of the subject device can operate on iOS / Android / Windows operating system whereas the application of

Standard Feature	The SONON Ultrasound Imaging System, Model: SONON 500L K# Unknown (Subject Device)	The SONON Ultrasound Imaging System, Model: SONON 300L K170085 (Predicate Device #2)	**Comparison**
			the predicate device only can operate on iOS and Android. However, all applications running on each operating system are compiled from the same source code and managed as one software. Therefore, there are no functional differences between the application running on Windows and others in the perspective of the device's safety and effectiveness.
Patient-Contacting Materials	All patient-contact materials are biocompatible and can be disinfected	All patient-contact materials are biocompatible and can be disinfected	Both devices comply with ISO 10993-1.
Reusable?	Yes	Yes	Identical
Duration of Use	Limited (<24 hours)	Limited (<24 hours)	Identical

7. Determination of Substantial Equivalence

The SONON Ultrasound Imaging System, Model: SONON 500L 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 500L is considered substantially equivalent to the predicate devices

8. Non-clinical Test Summary

The SONON Ultrasound Imaging System, Model: SONON 500L 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. Biocompatibility

Healcerion have applied ISO 10993 series to the 500L. Healcerion conducted biocompatibility studies of the patient-contacting surfaces in accordance with ISO 10993-1:2018: “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.” As per ISO 10993, Healcerion conducted cytotoxicity, sensitization, and irritation/intracutaneous reactivity tests for patient-contacting materials of the 500L.

Biocompatibility testing was conducted in accordance with the international standard below. The final product of SONON 500L including the patient-contacting surfaces of the device (probe nosepiece and lens) was evaluated for cytotoxicity, skin irritation and skin sensitization. The test results demonstrated that the patient-contacting surfaces of the probe are biocompatible.

Standard	Contents
ISO 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
ISO 10993-23:2021	Biological evaluation of medical devices — Part 23: Tests for irritation
ISO 10993-10:2021	Biological evaluation of medical devices — Part 10: Tests for skin sensitization

B. Cleaning and disinfection effectiveness

All the components and accessories of the SONON ULTRASOUND IMAGING SYSTEM are reusable (e.g., probe, battery pack, power cords, etc.). The probe is a non-critical, and its surface is only contact to the intact-skin of the patient. The 500L probe requires the user to process the probe (inspect, clean, and disinfect) for initial use, as well as after each use.

The intended use, the patient-contact materials (probe lens and probe nosepiece), and the instructions for inspecting, cleaning, and disinfecting the 500L probe are similar to the information submitted for and accepted by FDA for the SONON 300C under K151339.

C. Thermal, electrical, mechanical safety & Electromagnetic Compatibility

The SONON 500L complies with the electrical safety and electromagnetic compatibility requirements established by the standards below:

Standard	Contents
ES 60601-1 (Edition 3.1)	General requirements for basic safety and essential performance
IEC 60601-1-2 (Edition 4.0)	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 (Edition 2.1)	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 62133-2 (Edition 1.0)	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

D. Software Validation

The SONON 500L utilizes original software and OTS operating system. The SONON 500L contains MODERATE level of concern software. Software was designed and developed according to a software development process and was verified and validated. Software information is provided in accordance with FDA guidance: “The content of premarket submissions for software contained in medical devices, on May 11, 2005.”

E. Performance Test

Additional modes (M (Motion), CF (Color Flow), and PW (Pulsed Wave) mode) have been introduced to the subject device, and therefore, acoustic output test was conducted. The corresponding acoustic output levels were measured, calculated, and derated following the most recently released revision of the FDA-recognized consensus standard, IEC 62359. The results show that the changes in SONON 500L does not introduce risk related to excess acoustic output

Bench testing was used to evaluate the specified parameter related to the basic performance and the output of the ultrasound equipment. The test results show that the SONON 500L met all performance requirements.

F. Clinical tests and animal studies - not conducted

The subject of this premarket submission, SONON Ultrasound Imaging System (Model: SONON 500L), requires no clinical studies to support substantial equivalence.

G. Wireless Coexistence

Healcerion conducted the wireless coexistence test of SONON 500L which complies with ANSI C63.27:2017. Also, Healcerion updated the risk management files in accordance with AAMI TIR69:2017: “Risk management of radio-frequency wireless coexistence for medical devices and systems.”

9. Summary

In conclusion, the conducted tests, as well as all verification and validation activities, demonstrate that the design specifications and technological characteristics of the SONON Ultrasound Imaging System, Model: SONON 500L meet applicable requirements and standards for the safety and effectiveness of the device for its intended use. The testing and validation activities conducted demonstrate that any differences between the subject device and the predicate device do not raise new or different questions of safety or effectiveness as compared to the primary predicate device (K192107). Therefore, the SONON Ultrasound Imaging System, Model: SONON 500L is substantially equivalent in safety and effectiveness to the primary predicate device (K192107).