FCU Co., Ltd.
℅ Lee Hee Yeon
RA Manager
B-620/621, Biz Center, 17, Techno 4-ro
Yuseong-gu, Daejeon 34013
REPUBLIC OF KOREA

July 23, 2021

Re: K210468
Trade/Device Name: SC1 Handheld Ultrasound Imaging System (Model: SC1)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: May 18, 2021
Received: June 16, 2021

Dear Lee Hee Yeon:

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,

For

Thalia T. Mills, Ph.D.
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)*

K210468

Device Name

SCI Handheld Ultrasound Imaging System (Model SC1)

Indications for Use *(Describe)*

The SC1 Handheld Ultrasound Imaging System (Model: SC1) 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) through B mode.

SC1 is a transportable ultrasound system intended for use in environments where healthcare is provided by appropriately trained healthcare professionals.

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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FCU Co., Ltd.

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510(k) Summary

[As required by 21 CFR 807.92]

K210468

1. Date Prepared [21 CFR 807.92(a)(a)]

Feb 8, 2021

2. Submitter's Information & Contact Person [21 CFR 807.92(a)(1)]

- Name of Manufacturer: FCU Co., Ltd.
- Address: B-620/621, Biz Center, 17, Techno 4-ro, Yuseong-gu, Daejeon, 34013, Republic of Korea
- Contact Name: Lee Hee Yeon/ RA manager
- Telephone No.: +82-42-936-9078
- Fax No.: +82-42-936-9077
- Email Address: emma@fcultrasound.com

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Common name: Handheld ultrasound imaging system
Trade name: SC1 Handheld Ultrasound Imaging system (Model: SC1)

Classification Description	21 CFR Section	Product Code
Ultrasonic Pulsed Echo Imaging System	21 CFR 892.1560	IYO
Diagnostic Ultrasound Transducer	21 CFR 892.1570	ITX

As stated in 21 CFR, parts 892.1560, and 892.1570, each of these generic types of devices has been classified as Class II.

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4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow:

Predicate device

- 510(k) Number: K170085
- Applicant: Healcerion Co., Ltd.
- Classification Name: Diagnostic Ultrasound System and Transducer
- Trade Name: SONON Ultrasound Imaging System, Model: 300L

Reference device

- 510(k) Number: K192226
- Applicant: Philips Healthcare
- Classification Name: Diagnostic Ultrasound System and Transducer
- Trade Name: Lumify Diagnostic Ultrasound System

5. Description of the Device [21 CFR 807.92(a)(4)]

The SC1 Handheld ultrasound imaging system, Model: SC1, is a general purpose, software-controlled, diagnostic ultrasound system that uses pulsed-echo technology (B Mode (2D); Frequency: 5 - 13 MHz; module: linear; depth max: 10 cm) to transmit ultrasound images via wired communication to a mobile device that utilizes the Android operating system. Its function is to acquire ultrasound data and to display the data in operation.

The minimum requirements for the mobile devices that utilize the Android operating system for use with the SC1 Handheld ultrasound imaging system, Model: SC1 are as follows:

Item	Minimum Requirement
Recommended Tablet Device	Galaxy Tab S6 or later
Mobile OS Version	Android 9.0 or later

The SC1 Handheld ultrasound imaging system is a portable, general-purpose, software-controlled, hand-held diagnostic ultrasound system that consists of (i) the battery-operated, SC1L (Linear type Ultrasound Probe) that communicates wired with Android mobile device, (ii) the software that runs as an app on the mobile device, (iii) batteries, charger (Cradle), cable, power cord, and magnetizers (option), (iv) the instructions for use manual.

The SC1 App software can be downloaded to an Android mobile device and utilizes an icon touch-based user interface. The software enables ultrasound image review, controls for depth, gain, linear measurement

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The SC1 App software allows the user to image in real time and review freeze-frame images on the screen in a B-Mode, 2-dimensional scan format.

SC1 Handheld ultrasound system is only intended for acquisition and real time diagnosis. SC1 Handheld ultrasound system (SC1 probe and SC1 app) is not intended to provide any function on patient data (entering new patient information, editing patient data saving, storing, or transferring or exporting patient information). It does not have capability to connect to the PACS or equivalent DICOM network or export any patient data via USB cable.

Physician who is responsible for interpreting ultrasound images must be available in the room to provide diagnosis in real time.

The SC1 Handheld 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 [21 CFR 807.92(a)(5)]

The SC1 Handheld Ultrasound Imaging System (Model: SC1) 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) through B mode.

SC1 is a transportable ultrasound system intended for use in environments where healthcare is provided by appropriately trained healthcare professionals.

7. Determination of Substantial Equivalence [21 CFR 807.92(a)(6) and 21 CFR 807.92(b)]

There are no significant differences in the technological characteristics of this device compared to the predicate device which adversely affect safety or effectiveness. Provided below is a table summarizing and comparing the technological characteristics of the SC1 and the predicate devices:

	Proposed Device	Predicate Device	Reference Device	SE decision
K Number	To be assigned	K170085	K192226	-
Manufacturer	FCU Co., Ltd.	Healcerion Co., Ltd.	Philips Healthcare	-
Model	SC1	300L	Lumify Diagnostic Ultrasound System	-
Indications for Use	The SC1 Ultrasound Imaging System (Model: SC1) is intended for	Intended for ultrasound echo imaging, measurement, and	Philips Lumify Diagnostic Ultrasound System is intended for diagnostic	Equivalent*

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	Proposed Device	Predicate Device	Reference Device	SE decision
	diagnostic ultrasound echo imaging, measurement, and analysis of the human body for general clinical applications including musculoskeletal (MSK), vascular, small parts (breast, thyroid). SC1 is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.	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.	ultrasound imaging in B (2D), Color Doppler, Combined (B+Color), and M modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Fetal/Obstetric, Abdominal, Pediatric, Cephalic, Urology, Gynecological, Cardiac Fetal Echo, Small Organ, Musculoskeletal, Peripheral Vessel, Carotid, Cardiac. Lumify is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.	
Environment of Use	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Same
Acoustic Output Levels	- Compliance with IEC 60601-2-37:2007+ AMD1:2015 - Below Track 3 FDA limits in accordance with June 2019 ultrasound systems guidance document	- Compliance with IEC 60601-2-37:2007+ AMD1:2015 - Below Track 3 FDA limits in accordance with Sept. 2008 ultrasound systems guidance document	- Compliance with IEC 60601-2-37:2007+ AMD1:2015 - Below Track 3 FDA limits in accordance with Sept. 2008 ultrasound systems guidance document	Same
Imaging Capabilities	• Mode B (2D)	• pulsed-echo and Doppler ultrasound • Mode B (2D), Color scan	Mode B (2D), Color Doppler, Combined (B+Color), and M modes	Equivalent*
Patient Population	For use in all patients	For use in all patients	For use in all patients	Same
Anatomic Structures	• Musculoskeletal (MSK) • Vascular • Small parts (breast, thyroid)	• Musculoskeletal (MSK) • Vascular • Small parts (breast, thyroid) • Thoracic/pleural motion • Fluid detection	• Fetal/Obstetric • Abdominal • Pediatric • Cephalic • Urology • Gynecological • Cardiac Fetal Echo • Small Organ	Equivalent*

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	Proposed Device	Predicate Device	Reference Device	SE decision
			• Musculoskeletal • Peripheral Vessel • Carotid • Cardiac	
Users	Healthcare professionals	Healthcare professionals	Healthcare professionals	Same
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.	Same
Probe Characteristics	Linear, 5 - 13MHz	Linear, 5MHz / 7.5MHz / 10MHz frequency	Linear, 4 – 12 MHz Curved, 2 – 5 MHz Phased, 1 – 4 MHz	Equivalent**
Probe Connection to Display	Wired	Wireless	Wired	Equivalent***
Off-the-shelf operating system	Android	iOS / Android	Android	Equivalent***
Software	Runs as an app on off-the-shelf mobile device	Runs as an app on off-the-shelf mobile device	Runs as an app on off-the-shelf mobile device	Same
System Components	• Ultrasound Probe • FCradle (Cradle) • AC/DC adapter including Power Cable • Communication Cable (USB Cable) • Batteries • Tablet (mobile device): Not provided. • User Manual • Magnetizer (Option) - long/short type - cap cover	• Ultrasound Probe • Battery Charger (Cradle) • AC/DC adapter • Power cable • Battery Pack • Tablet (mobile device): Not provided. • User Manual	• Ultrasound Probe • USB transducer cable • USB-C transducer cable • USB Micro-B transducer cable • Android device (mobile device): • User Manual	Equivalent***
Patient-Contacting	Tested by ISO 10993-5 Tested by ISO 10993-10	Tested by ISO 10993-5 Tested by ISO 10993-10	Tested by ISO 10993-5 Tested by ISO 10993-10	Same

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	Proposed Device	Predicate Device	Reference Device	SE decision
Materials				

* The proposed device supports only Mode B (2D) to transport the convenience of moving the device. Therefore, the scope of clinical application is more limited than that of the predicate device. But the differences do not raise any new potential safety risks and therefore, we believe there is no impact on safety or efficacy for the proposed device. This is described in the User's Manual, so the user will be aware of this.

** This device supports only linear type probe, and the frequency range of the probe is equivalent with the range of the predicate device. The differences indicated, do not raise any new potential safety risks and therefore, there is no impact on safety or efficacy for the proposed device.

*** The technical differences do not raise any new potential safety risks and therefore, there is no impact on safety or efficacy for the proposed device.

Non-Clinical Test Summary [21 CFR 807.92(b)(1)]

1) Electrical Safety, Electromagnetic Compatibility Testing

Bench tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

Standard (Edition)	Standard Title	Consensus Standard
IEC 60601-1:2005/A1:2012 (3.1 edition) + National Difference	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Yes
IEC 60601-1-2:2014 (4.0 edition)	Medical electrical equipment - Part 1-2: General requirements for safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	Yes
IEC 60601-1-6:2010/AMD1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	Yes

2) Software Validation and Cybersecurity Management

The SC1 contains MODERATE level of concern software. The software was designed and developed according to a software development process and was verified and validated. The software information is provided in accordance with FDA guidance: The content of premarket submissions for software contained in medical devices, on May 11, 2005 and "Premarket Management of Cybersecurity in Medical Devices issued on December 28, 2016" and "ISO 14971:2007 Medical Devices – Application of Risk Management to Medical Devices".

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3) Biocompatibility

The part of SC1 in contact with the patient was verified and demonstrated for the safety of materials through the biocompatibility test in accordance with ISO 10993-1:2018.

- Cytotoxicity test according to ISO 10993-5:2009
- Intracutaneous (intradermal) reactivity test according to ISO 10993-10:2010
- Skin sensitization test according to ISO 10993-10:2010

4) Performance Testing

Through compliance with the identified current standards, the safety and effectiveness of the device is supported.

The additional performance test has been conducted to support the technological characteristics of the SC1. The performance of the SC1 has been defined as follows.

- Axial, Lateral Resolution
- Axial, Lateral distance
- B-mode display
- Max depth

Clinical Test Summary [21 CFR 807.92(b)(2)]

No clinical studies were considered necessary and performed.

8. Conclusion [21 CFR 807.92(b)(3)]

In conclusion, the tests conducted, as well as all verification and validation activities, demonstrate that the design specifications and technological characteristics of the SC1 Handheld ultrasound imaging system (Model: SC1) 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 predicates and proposed device, but those differences do not raise new or different questions of safety or effectiveness as compared to the predicate devices. Therefore, the SC1 Handheld ultrasound imaging system (Model: SC1) is substantially equivalent to the currently marketed predicate device.