June 26, 2024

FCU Co., Ltd.
℅ Song Hyuk
RA manager
B-620/621, Biz Center, 17, Techno 4-ro
Yuseong-gu, Daejeon 34013
REPUBLIC OF KOREA

Re: K233579
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, IYN, ITX
Dated: May 31, 2024
Received: May 31, 2024

Dear Song Hyuk:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233579

Device Name

SC1 Handheld Ultrasound Imaging system (Model: SC1)

Indications for Use *(Describe)*

The SC1 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. Flow detection is possible using PWD (Power Doppler) mode.

SC1 is a transportable ultrasound system intended for use in environments where healthcare is provided by 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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510(k) Summary

[As required by 21 CFR 807.92]

1. Date Prepared

May 31, 2024

2. Submitter's Information & Contact Person

- Name of Manufacturer: FCU Co., Ltd.
- Address: 2F, 62-4, Techno 1-ro, Yuseong-gu, Daejeon, Republic of Korea (34014)
- Contact Name: Song Hyuk/ RA manager
- Telephone No.: +82-42-936-9078
- Fax No.: +82-42-936-9077
- Email Address: h.song@fcultrasound.com

3. Trade Name, Common Name, Classification

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

Classification Description	21 CFR Section	Product Code
Ultrasonic Pulse Doppler Imaging System	21 CFR 892.1550	IYN
Ultrasonic Pulsed Echo Imaging System	21 CFR 892.1560	IYO
Diagnostic Ultrasound Transducer	21 CFR 892.1570	ITX

As stated in 21 CFR, parts 892.1550, and 892.1560, and 892.1570, each of these generic types of devices has been classified as Class II.

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4. Predicate Device

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

Primary Predicate device

- 510(k) Number: K210468
- Applicant: FCU Co., Ltd.
- Classification Name: Diagnostic Ultrasound System and Transducer
- Trade Name: SC1 Handheld Ultrasound Imaging system (Model: SC1)

Reference device

- 510(k) Number: K192226
- Applicant: Philips Healthcare
- Classification Name: Ultrasonic Pulse Doppler Imaging System
- Trade Name: Lumify Diagnostic Ultrasound System

These predicates have not been subject to a design-related recall.

No reference devices were used in this submission.

5. Device Description

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) and PD Mode (Power Doppler); 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 14.0 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.

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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

The SC1 App software allows the user to image in real time and review freeze-frame images on the screen in a B-Mode and PD-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) provides functions on patient data (entering new patient information, editing patient data saving, storing, or transferring or exporting patient information). It is possible to connect to the PACS DICOM network (hospital network) to get the list of exams and export recorded exams. However, there is no option to export patient data via a USB cable

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

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

The SC1 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. Flow detection is possible using PD (Power Doppler) mode.

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

7. Comparison of Technical Characteristics with the Predicate Device.

The subject device does not have any hardware changes compared to primary predicate device. There are only software changes. The intended use and basic technical characteristics are the same.

The following technological differences exist between the subject and predicate devices:

- Use of Power doppler Mode, flow detection is possible using PD (Power Doppler) mode.
- Use of DICOM, it provides all the features for patient data (enter new patient information, edit patient data, store, store patient data, send or export patient information). This feature can only connect to the PACS DICOM network (Hospital Network) to get a list of tests and export recorded tests. There is no option to export patient data over a USB cable.

There are no significant differences in the technological characteristics of this device compared to the predicate device which adversely affect safety or effectiveness.

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8. Determination of Substantial Equivalence

Provided below is a table summarizing and comparing the technological characteristics of the subject device and the predicate devices:

	Subject Device	**Primary Predicate Device**	**Reference Device**	**SE decision**
K Number	To be assigned	K210468	K192226	-
Manufacturer	FCU Co., Ltd.	FCU Co., Ltd.	Philips Healthcare	-
Model	SC1	SC1	Lumify Diagnostic Ultrasound System	-
Indications for Use	The SC1 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. Flow detection is possible using PD (Power Doppler) mode. SC1 is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.	The 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). SC1 is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.	Philips Lumify Diagnostic Ultrasound System is intended for diagnostic 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.	Equivalent*
Environment of Use	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Hospital, clinic, and medical office settings	Equivalent
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 June 2019 ultrasound systems guidance document	- Compliance with IEC 60601-2-37:2007+ AMD1:2015 - Below Track 3 FDA limits in accordance with June 2019 ultrasound systems guidance document	Equivalent

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	Subject Device	**Primary Predicate Device**	**Reference Device**	**SE decision**
Imaging Capabilities	• Mode B (2D) • Combined (B+Power Doppler)	• Mode B (2D)	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	Equivalent
Anatomic Structures	• Musculoskeletal (MSK) • Vascular • Small parts (breast, thyroid)	• Musculoskeletal (MSK) • Vascular • Small parts (breast, thyroid)	• Fetal/Obstetric • Abdominal • Pediatric • Cephalic • Urology • Gynecological • Cardiac Fetal Echo • Small Organ • Musculoskeletal • Peripheral Vessel • Carotid • Cardiac	Equivalent*
Users	Healthcare professionals	Healthcare professionals	Healthcare professionals	Equivalent
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.	Equivalent
Probe Characteristics	Linear, 5 - 13MHz	Linear, 5 - 13MHz	Linear, 4 – 12 MHz Curved, 2 – 5 MHz Phased, 1 – 4 MHz	Equivalent**
Probe Connection to Display	Wired	Wired	Wired	Equivalent
Off-the-shelf operating system	Android	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	Equivalent
System Components	• Ultrasound Probe	• Ultrasound Probe	• Ultrasound Probe • USB transducer cable	Equivalent***

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	Subject Device	Primary Predicate Device	Reference Device	SE decision
	• 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	• 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	• USB-C transducer cable • USB Micro-B transducer cable • Android device (mobile device): • User Manual	
Patient-Contacting Materials	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	Equivalent

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

9. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

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:

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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 (4.1 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
IEC 60601-2-37:2007/AMD1:2015	Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	Yes

2) Software Validation and Cybersecurity Management

The SC1 contains basic documentation 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 "IEC 62304:2006+AMD1:2015", "ANSI/UL 2900-1:2017" and FDA guidance: The Content of Premarket Submissions for Device Software Functions, June, 2023 and "Cybersecurity in Medical Devices: Quality System considerations and Content of Premarket Submissions, September, 2023" and "ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices".

3) Biocompatibility Testing

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 and Combined(B+PD) mode display
- Max depth

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

No clinical studies were considered necessary and performed.

10. 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 subject 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 subject device, predicate device and reference device, but those differences do not raise new or different questions of safety or effectiveness as compared to the predicate device and reference device. Therefore, the subject SC1 Handheld ultrasound imaging system (Model: SC1) is substantially equivalent to legally marketed predicate device and reference device.