December 10, 2024

Shantou Institute of Ultrasonic Instruments Co., Ltd.
Guang Chen
Regulatory Affairs Compliance Office
#77, Jinsha Road
Shantou, CN 515041
CHINA

Re: K243132
Trade/Device Name: Digital Color Doppler Ultrasound Imaging System (Readius L15); Digital Color Doppler Ultrasound Imaging System (Readius P8); Digital Color Doppler Ultrasound Imaging System (Readius V6); Digital Color Doppler Ultrasound Imaging System (Readius C6)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: September 24, 2024
Received: September 30, 2024

Dear Guang Chen:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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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.

510(k) Number *(if known)*
k243132

Device Name
Digital Color Doppler Ultrasound Imaging System (Readius L15); Digital Color Doppler Ultrasound Imaging System (Readius P8); Digital Color Doppler Ultrasound Imaging System (Readius V6); Digital Color Doppler Ultrasound Imaging System (Readius C6)

Indications for Use *(Describe)*
Readius L15/ Readius P8/ Readius V6/ Readius C6 Digital Color Doppler Ultrasound Imaging System is a general purpose diagnostic ultrasound system intended to be used by a trained/qualified physician in a hospital or clinical setting for ultrasound evaluation of abdominal, small organ (thyroid, testes, breast), and peripheral vascular applications in B-Mode, M-mode, Color Flow Map (CFM), Vector Space Flow (VS Flow), Color Power Angio (CPA), Pulsed Wave (PW) and Panoscope.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This summary of 510(k) safety and effectiveness information is provided in accordance with the requirements of SMDA 1990 and 21 CFR 807.92(c).

The assigned 510(k) number is: K243132

5.1 Submitter

Shantou Institute of Ultrasonic Instruments Co., Ltd. (SIUI)

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77 Jinsha Road, Shantou, Guangdong 515041, China

Date Prepared: September 30, 2024

5.2 Device

Name of Device:

Readius L15 Digital Color Doppler Ultrasound Imaging System

Readius P8 Digital Color Doppler Ultrasound Imaging System

Readius V6 Digital Color Doppler Ultrasound Imaging System

Readius C6 Digital Color Doppler Ultrasound Imaging System

510(k) submitter: SIUI

Classification Name:

Ultrasonic pulsed Doppler imaging system	90-IYN	(per 21 CFR 892.1550)
Ultrasonic pulsed echo imaging system	90-IYO	(per 21 CFR 892.1560)

Diagnostic ultrasonic transducer	90-ITX	(per 21 CFR 892.1570)

Regulatory Class: II

Product Code: IYN, IYO, ITX

5.3 Predicate Device

Name of Predicate Device:

Apogee 2300 Digital Color Doppler Ultrasound Imaging System (K173000)

510(k) holder: SIUI

Regulatory Class: II

Product Code: IYN, IYO, ITX

Classification Name:

Ultrasonic pulsed Doppler imaging system	90-IYN	(per 21 CFR 892.1550)
Ultrasonic pulsed echo imaging system	90-IYO	(per 21 CFR 892.1560)
Diagnostic ultrasonic transducer	90-ITX	(per 21 CFR 892.1570)

5.4 Device Description

5.4.1 Description

Readius L15/ Readius P8/ Readius V6/ Readius C6 Digital Color Doppler Ultrasound Imaging System is a general purpose diagnostic ultrasound system intended to be used by a trained/qualified physician in a hospital or clinical setting for ultrasound evaluation of abdominal, small organs (thyroid, testes, breast), and peripheral vascular applications in B-Mode, M-mode, Color Flow Map (CFM), Vector Space Flow (VS Flow), Color Power Angio (CPA), Pulsed Wave (PW) and Panoscope.

The system is designed for use in linear, convex, phased array scanning modes and supports linear, convex and phased array transducers. The system has cine review, image zoom, measurements and calculations, image storage, review and recording capabilities.

This system is a Track 3 device and the software used in Readius L15/ Readius P8/

Readius V6/ Readius C6 Digital Color Ultrasound Imaging System is Ultrasound Software developed by SIUI and is based on the predicate device. The software documentation level is Basic Documentation Level.

5.4.2 Comparisons of Readius L15/ Readius P8/ Readius V6/ Readius C6 devices

The Readius Series use the same safe critical components, with the same circuit modules and working principles. The mechanical structure is designed for the market requirements of the devices according to the requirements of international general safety standard (IEC 60601-1). The hardware design is exactly the same for the Readius Series. Subject to market positioning, the Readius L15/ Readius P8/ Readius V6/ Readius C6 have different probe configurations. See the table below.

Product Model		Readius L15	Readius P8	Readius V6	Readius C6
Photo					
Configura-tion of product functions	C3	√	√	√	√
	C6	√	√	√	○
	L8	√	√	○	√
	P3	√	○	√	√

Note: "√" means "standard configuration", "○" means "optional configuration".

5.5 Indications for Use

The Readius L15/ Readius P8/ Readius V6/ Readius C6 Digital Color Doppler Ultrasound Imaging System is a general purpose diagnostic ultrasound system intended to be used by a trained/qualified physician in a hospital or clinical setting for ultrasound evaluation of abdominal, small organs (thyroid, testes, breast), and peripheral vascular applications in B-Mode, M-mode, Color Flow Map (CFM), Vector Space Flow (VS Flow), Color Power Angio (CPA), Pulsed Wave (PW) and Panoscope.

5.6 Comparison of Technological Characteristics with the Predicate Device

The Readius L15/ Readius P8/ Readius V6/ Readius C6 Digital Color Doppler Ultrasound Imaging Systems are multi-purpose diagnostic ultrasound systems with accessories and proprietary software, and are substantially equivalent to the predicate device.

Type	Manufacturer	Device	510 (K) Number
Predicate device	SIUI	Apogee 2300 Digital Color Doppler Ultrasound Imaging System	K173000

The intended use and technical specifications on the SIUI Readius L15/ Readius P8/ Readius V6/ Readius C6 covered by substantial equivalence to devices currently having FDA 510(k) clearance is SIUI Apogee 2300 Digital Color Doppler Ultrasound Imaging System (K173000).

For the transducers on the SIUI Readius L15/ Readius P8/ Readius V6/ Readius C6, the claim of substantial equivalence to devices currently having FDA 510(k) clearance is SIUI Apogee 2300 Digital Color Doppler Ultrasound Imaging System (K173000).

Intended Use Comparison:

Compared with the predicate device Apogee 2300 (K173000), the Subject Devices have fewer indications.

Technical Characteristics Comparison:

The Readius L15/ Readius P8/ Readius V6/ Readius C6 uses WiFi to transmit image signals acquired by the probe to the handheld device (IOS or Android device) for display. It is different from the predicate device Apogee 2300 (K173000). The operation mode of the device is also different from the predicate device Apogee 2300, but it is the same as the predicate device Apogee 2300 in terms of imaging principle, imaging mode, image magnification, etc.

Acoustic Power Levels Comparison:

The Acoustic power levels of subject devices meet the limits of FDA, the same as the predicate device Apogee 2300 (K173000).

Materials of Probes Comparison:

The materials of probes for the subject devices are same as the predicate device Apogee 2300 (K173000).

Probes Comparison:

The Readius L15/ Readius P8/ Readius V6/ Readius C6 has similar probes as the predicate device of Apogee 2300. Applications for these probes are within the indications for use of the predicate device Apogee 2300 (K173000).

Any differences between the predicate and the new device have no impact on safety or efficacy of the new device and do not raise any new potential or increased safety risks, and the new device is equivalent in performance to existing legally marketed devices.

5.7 Non-clinical Testing Summary

The Readius L15/ Readius P8/ Readius V6/ Readius C6 Digital Color Doppler Ultrasound Imaging Systems comply with and/or were tested in accordance with the following FDA guidance and International Standards:

- IEC 60601-1:2005+ AMD1:2012+AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-2-37:2007+A1:2015 Medical electrical equipment - Part 2-37:Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
- IEC 60601-2-25:2011 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
- ISO 14971:2019 Medical devices - Application of risk management to medical devices
- ISO 10993-1:2018 Biological evaluation of medical devices - Part1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices - Part5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021 Biological evaluation of medical devices - Part 10:Tests for skin sensitization
- ISO 10993-23:2021 Biological evaluation of medical devices - Part 23:Tests for

irritation

- IEC 62304:2006+A1:2015 Medical device software – Software life cycle processes
- IEC 60601-1-6:2010+ AMD1:2013+AMD2:2020 Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 62366-1: 2015+AMD1:2020 Medical devices – Part 1: Application of usability engineering to medical devices
- ISO 15223-1:2021 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Marketing Clearance of Diagnostic Ultrasound Systems and Transducers

The subject device and the predicate device are comparable in terms of technical features, general functions, applications and intended uses. The test results showed compliance with the above standards. The non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate device.

5.8 Clinical Testing

Clinical testing is not necessary for the Readius L15/ Readius P8/ Readius V6/ Readius C6 Digital Color Doppler Ultrasound Imaging System in order to demonstrate substantial equivalence to the predicate device.

5.9 Conclusion

The subject device Readius L15/ Readius P8/ Readius V6/ Readius C6 Digital Color Doppler Ultrasound Imaging System and the predicate device SIUI Apogee 2300 Digital Color Doppler Ultrasound Imaging System are comparable in terms of technical features, general functions, applications and indications for use. Therefore,

The Readius L15/ Readius P8/ Readius V6/ Readius C6 Digital Color Doppler Ultrasound Imaging System is substantially equivalent with respect to safety and effectiveness of the predicate device currently cleared for market.