Siemens Medical Solutions USA, Inc.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL, MN 55114

April 1, 2021

Re: K210743
Trade/Device Name: ACUSON Redwood Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, OIJ
Dated: March 11, 2021
Received: March 12, 2021

Dear Prithul Bom:

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)*

K210743

Device Name
ACUSON Redwood Diagnostic Ultrasound System

Indications for Use *(Describe)*

The ACUSON Redwood ultrasound imaging system is intended to provide images of, or signals from, inside the body by an appropriately trained healthcare professional in a clinical setting for the following applications: Fetal, Abdominal, Pediatric, Small Parts, OB/GYN (useful for visualization of the ovaries, follicles, uterus, and other pelvic structures), Adult, Pediatric and Neonatal Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The systems also provide the ability to measure anatomical structures for fetal, abdominal, pediatric, small organ, neonatal cephalic, cardiac (adult, pediatric and neonatal), trans-esophageal, transrectal, transvaginal, peripheral vessel, musculoskeletal (conventional), musculo-skeletal (superficial) and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Mode of operation:
2D-mode
2D-mode with Harmonics imaging
Color flow Doppler
Color (velocity)
Power (energy)
Doppler Tissue Imaging
Pulsed Wave Doppler
Pulsed Wave Doppler Tissue Imaging
High Pulsed Repetition Frequency Pulsed Wave Doppler
Continuous Wave Doppler
Steerable Continuous Wave Doppler for phased array transducers
Auxiliary Continuous Wave Doppler for pencil transducers
M-mode
M-mode with Harmonics imaging
Anatomical M-mode
Volume Imaging
Combined Modes
2D-mode with color
2D-mode with power
2D/Doppler
2D/Doppler with color
2D/Doppler with power
2D/M-mode
2D/M-mode with color
2D/Anatomical M-mode

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

K210743

Date: January 15, 2021

1. Sponsor:

Siemens Medical Solutions USA, Inc.
Ultrasound Division
22010 South East 51st Street
Issaquah, Washington 98029

Contact Person: Sulgue Choi
Tel: (425) 281-9898

2. Device Name: ACUSON Redwood Diagnostic Ultrasound System

Common Name: Diagnostic Ultrasound System with Accessories

Classification:

Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology

Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX
Biopsy Needle Guide Kit	892.1560	90-OIJ

Manufacturing Site:

Siemens Healthineers, Ltd.
2nd ~ 3rd Floor, 143, Sunhwan-ro, Jungwon-gu, Seongnam-si,
Gyeonggi-do, Republic of Korea

Siemens Medical Solutions USA, Inc.
22010 South East 51st Street,
Issaquah, Washington 98029, UNITED STATES

3. Legally Marketed Predicate Devices

The ACUSON Redwood Diagnostic Ultrasound System is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to the company's own products, the ACUSON P200 (K191922) which is a primary predicated device, Sequoia (K201462) and the ACUSON S family (K172162).

4. Device Description

The ACUSON Redwood Diagnostic Ultrasound System is a multi-purpose mobile, software controlled, diagnostic ultrasound system with an on-screen display of thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to transmit and receive ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Color M Mode, Doppler Tissue Mode, Amplitude Doppler Mode, a combination of modes and Harmonic Imaging on a Display.

5. Intended Use/Indications for Use

The ACUSON Redwood ultrasound imaging system is intended to provide images of, or signals from, inside the body by an appropriately trained healthcare professional in a clinical setting for the following applications: Fetal, Abdominal, Pediatric, Small Parts, OB/GYN (useful for visualization of the ovaries, follicles, uterus, and other pelvic structures), Adult, Pediatric and Neonatal Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.
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M-mode
M-mode with Harmonics imaging
Anatomical M-mode
Volume Imaging
Combined Modes
2D-mode with color
2D-mode with power
2D/Doppler
2D/Doppler with color
2D/Doppler with power
2D/M-mode
2D/M-mode with color
2D/Anatomical M-mode

6. Summary of Technological Characteristics

The modified ACUSON Redwood Ultrasound System is the equivalent as the company's own previously cleared ACUSON P200 (K191922), ACUSON Sequoia (K201462) and the ACUSON S family (K172162) with regard to both intended use and technological characteristics. Both the modified ultrasound system under this review and the predicate ultrasound systems function in the same manner as all diagnostic ultrasound systems and transducers.

The submission device differs from the predicated devices as following:

- The modified ACUSON Redwood Ultrasound System includes the addition of the 9VE4 transducer previously cleared on the ACUSON Sequoia (K201462).
- The modified ACUSON Redwood Ultrasound System includes the addition of the 18H6 transducer previously cleared on the ACUSON Sequoia (K201462).
- The modified ACUSON Redwood Ultrasound System includes the addition of the 7VC2 transducer, which is substantially equivalent to the 7CF2 transducer previously cleared on the ACUSON S family (K172162).
- The modified ACUSON Redwood Ultrasound System includes the addition of the 3D/4D feature, which is substantially equivalent to the 3D/4D feature previously cleared on the ACUSON Sequoia (K201462).
- The modified ACUSON Redwood Ultrasound System includes the addition of the Freehand 3D feature, which is substantially equivalent to the 3-Scape real-time 3D Imaging option previously cleared on the ACUSON S family (K172162).

All other hardware and software features of the ACUSON Redwood Diagnostic Ultrasound device remain unchanged. The foundation of the ACUSON Redwood (this submission) is the ACUSON P200(K191922) with features and transducers integrated with the ACUSON P200(K191922) hardware and the ACUSON Redwood (this submission) reuse software developed for P200(K191922) mainly as well as 9VE4 transducer, 18H6 transducer and 3D/4D feature from Sequoia (K201462).

The submission device is substantially equivalent to the predicates with regards to both intended use and technological characteristics.

Feature / Characteristic	**ACUSON Redwood** This Submission	**ACUSON P200 K191922** Primary Predicate device	**ACUSON Sequoia K201462** Reference Predicate device	**ACUSON S Family K172162** Reference Predicate device
Indications for Use:				
▪ Fetal	√	√	-	-
▪ Abdominal	√	√	-	-
▪ Pediatric	√	√	-	-

Feature / Characteristic	**ACUSON Redwood** This Submission	**ACUSON P200 K191922** Primary Predicate device	**ACUSON Sequoia K201462** Reference Predicate device	**ACUSON S Family K172162** Reference Predicate device
▪ Small Organ	√	√	-	-
▪ Cardiac	√	√	-	-
▪ Neonatal Cephalic			-	-
▪ Trans-esophageal			-	-
▪ Transrectal	√	√	-	-
▪ Transvaginal	√	√	-	-
▪ Peripheral vessel	√	√	-	-
▪ Musculo-skeletal (conventional)	√	√	-	-
▪ Musculo-skeletal (superficial)	√	√	-	-
Frequencies Supported:	√ (1.0MHZ~18MHz)	√ (1.0MHZ~18MHz)	-	-
Modes:				
▪ B	√	√	-	-
▪ M	√	√	-	-
▪ PWD (Pulsed Wave Doppler)	√	√	-	-
▪ CWD (Continuous Wave Doppler)	√	√	-	-
▪ PW DTI (Doppler Tissue Image)	√	√	-	-
▪ Color Doppler	√	√	-	-
▪ Power Doppler	√	√	-	-
▪ Combined (BMDC)	√	√	-	-

Feature / Characteristic	**ACUSON Redwood** This Submission	**ACUSON P200** **K191922** Primary Predicate device	**ACUSON Sequoia** **K201462** Reference Predicate device	**ACUSON S Family** **K172162** Reference Predicate device
Features:				
▪ Harmonics	√	√	-	-
▪ Compounding	√	√	-	-
▪ UltraArt Universal Image processing	√	√	-	-
▪ Tissue Equalization (TEQ)	√	√	-	-
▪ Biopsy	√	√	-	-
▪ Clarify	√	√	-	-
▪ Cardiac Imaging	√	√	-	-
▪ Speed of Sound	√	√	-	-
▪ Protocols	√	√	-	-
▪ DICOM	√	√	-	-
▪ eSie Calcs	√	√	-	-
▪ Wireless	√	√	-	-
▪ Virtual Touch Strain Imaging	√	√	-	-
▪ Virtual Touch Point Shear Wave (VTIQ)	√	√	-	-
▪ Contrast Agent Imaging	√	√	-	-
▪ eSie OB	√	√	-	-
▪ eSie Left Heart	√	√	-	-
▪ eSie Measure	√	√	-	-
▪ eSie Follicle	√	√	-	-
▪ Panoramic Imaging	√	√	-	-

Feature / Characteristic	**ACUSON Redwood** This Submission	**ACUSON P200 K191922** Primary Predicate device	**ACUSON Sequoia K201462** Reference Predicate device	**ACUSON S Family K172162** Reference Predicate device
▪ Stress Echo	√	√	-	-
▪ Syngo Velocity Vector Imaging (VVI)	√	√	-	-
▪ eSieLink	√	√	-	-
▪ DICOM SR	√	√	-	-
▪ Wireless	√	√	-	-
▪ 3D/4D	√	-	√	-
▪ Freehand 3D Imaging	√	-	-	√
Monitor (OLED)	√ (22”)	√ (22”)	-	-
Touch Screen: adjustable display	√ (13.3”)	√ (13.3”)	-	-
Output Display Standard (Track 3)	√	√	-	-
Patient Contact Materials	Tested to ISO 10993-1	Tested to ISO 10993-1	-	-
UL 60601-1 Certified	√	√	-	-
Indications for Use	√	√	-	-

7. A brief discussion of nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety and have been found to conform to applicable medical device safety standards. The systems comply with the following voluntary standards:

- IEC 62359: Edition 2.1 2017-09, Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields / Combines IEC 62359 (2010-10) and AMD 1 (2017-09)
- Safety and EMC Requirements for Medical Equipment

- AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
- IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance / This document and its separate amendments continue to be valid together with the consolidated version
- IEC 60601-1-2 Edition 4.0 2014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-18: Edition 3.0 2009-08, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- IEC 60601-2-37 Edition 2.1 2015, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

- ISO 10993-1 Fifth edition 2018-08-01, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process / Corrected and reprinted in 2018-10

8. A summary discussion of the clinical tests submitted, referenced, or relied on for a determination of substantial equivalence.

Since the ACUSON Redwood Diagnostic Ultrasound System uses the same technology and principles as existing devices, clinical studies were not required to support substantial equivalence.

9. Summary

Intended uses and other key features are consistent with traditional clinical practice and FDA guidelines. The design and development process of the manufacturer conforms to 21 CFR 820 Quality System Regulation and ISO 13485:2016 quality system standards. The product is designed to conform to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound system has accumulated a long history of safe and effective performance. Therefore, it is the opinion of Siemens Medical Solutions USA, Inc. that the ACUSON Redwood system is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.