November 15, 2024

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

Re: K243299
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: October 18, 2024
Received: October 18, 2024

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 (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
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)*

K243299

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 Cephalic, Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, Transcranial, and Peripheral Vascular.
The system supports the Ultrasound-Derived Fat Fraction (UDFF) measurement tool to report an index that can be useful as an aid to a physician managing adult patients with hepatic steatosis.

The system also provides the ability to measure anatomical structures: fetal, abdominal, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac (adult, pediatric and neonatal), transesophageal, transrectal, transvaginal, peripheral vessel, musculoskeletal (conventional), musculoskeletal (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.

Operating Modes
• 2D-mode
– 2D-mode with Harmonic 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 Harmonic 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

K243299

Date: November 15, 2024

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

Contact Person: Shilpa Rapaka
Phone: 512-913-1053

Secondary Contact: Emily Woo
Phone: 82-10-4697-2683

2. Device Name: ACUSON Redwood Diagnostic Ultrasound System

Common Name: Diagnostic Ultrasound System with Accessories

Classification: Regulatory Class: II
Classification Panel: Radiology

Classification Name	21 CFR Section	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX
Biopsy Needle Guide Kit	892.1560	OIJ

Manufacturing Site: Siemens Healthcare s.r.o
Panattoni Park Kosice Airport ul.
Andreja Kvasa 5040 17, Kosice-Barca, Slovakia

3. Legally Marketed Predicate Device and Reference Device

The ACUSON Redwood Diagnostic Ultrasound System is multi-purpose diagnostic ultrasound system with proprietary software and optional accessories and is substantially equivalent to the company's own Ultrasound devices, the ACUSON Redwood (K210743) which is the primary predicate device and the ACUSON Sequoia (K232145) as the reference device.

4. Device Description

The ACUSON Redwood Diagnostic Ultrasound System is multi-purpose, mobile, software-controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to acquire harmonic 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 Image mode, Amplitude Doppler Mode, Combination modes, Harmonic Imaging and 3D Imaging modes, and 4D imaging modes on a flat panel display for diagnostic ultrasound imaging.

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 Cephalic, Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, Transcranial, and Peripheral Vascular.

The system supports the Ultrasound-Derived Fat Fraction (UDFF) measurement tool to report an index that can be useful as an aid to a physician managing adult patients with hepatic steatosis.

The system also provides the ability to measure anatomical structures: fetal, abdominal, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac (adult, pediatric and neonatal), transesophageal, transrectal, transvaginal, peripheral vessel, musculoskeletal (conventional), musculoskeletal (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.

Operating Modes

- 2D-mode
  - 2D-mode with Harmonic 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 Harmonic 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. Substantially Equivalent Devices and Summary of Technological Characteristics

The ACUSON Redwood Diagnostic Ultrasound System is substantially equivalent to the company's own Ultrasound devices that are already cleared for distribution in the United States. The predicate and reference devices of ACUSON Redwood are ACUSON Redwood (K210743) and ACUSON Sequoia (K232145) with regards to intended use, indications for use, technological characteristics (transducers, accessories, software features), safety, and effectiveness.

The submission device differs from the predicate/reference devices as follows:

- The addition of 9C2 transducer, which is substantially equivalent to 9C2 transducer previously cleared on the ACUSON Sequoia (K232145).
- The addition of Auto IMT (Intima-Media Thickness) feature, which is substantially equivalent to Auto IMT feature previously cleared on the ACUSON Sequoia (K232145).
- The addition of Virtual Touch UDFF (Ultrasound-Derived Fat Fraction) feature, which is substantially equivalent to Virtual Touch UDFF feature previously cleared on the ACUSON Sequoia (K232145).
- The addition of TCD (Transcranial doppler) Imaging, which is substantially equivalent to TCI previously cleared on the ACUSON Sequoia (K232145).
- The modified ACUSON Redwood Ultrasound System updated the indications for use statement (Intended use) to add Virtual Touch UDFF (Ultrasound-Derived Fat Fraction) indication and Transcranial clinical application for TCD which were previously cleared on the reference device, ACUSON Sequoia (K232145) where transcranial application was covered by Adult Cephalic.
- The addition of needle guides for 9C2 transducer and 9VE4 transducer, which are substantially equivalent to needle guides for 9C2 transducer and 9VE4 transducer previously cleared on the ACUSON Sequoia (K232145).
- The addition of Adult Cephalic and Abdominal clinical applications on 5V1 transducer and Neonatal Cephalic clinical application on 8V3 transducer, which is substantially equivalent to clinical applications of 5V1, 4V1 and 8V3 transducer previously cleared on the ACUSON Sequoia (K232145).

All other hardware and software features of the ACUSON Redwood Diagnostic Ultrasound devices remain unchanged. The foundation of the ACUSON Redwood (this submission) is the ACUSON Redwood (K210743) hardware. ACUSON Redwood (this submission) reuses software developed for ACUSON Redwood (K210743) and adds features such as 9C2 transducer, Auto IMT, Virtual Touch UDFF (Ultrasound-Derived Fat Fraction), TCD from ACUSON Sequoia (K232145).

7. Nonclinical Data

The subject devices have 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)
- 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/A1(2012), Medical electric 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, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- IEC 60601-1-6:2010+A1:2013+A2:2020 Medical Electrical Equipment Part 1-6, General Requirements for Basic Safety and Essential Performance- Collateral standard: Usability
- ANSI AAMI ISO 14971: Medical devices- Applications of risk management to medical devices, 2019
- FDA Ultrasound Guidance document, “Marketing Clearance of Diagnostic Ultrasound Systems and Transducers,” issued in February 2023 (https://www.fda.gov/media/71100/download) for determining the measurement accuracy

8. Clinical Data

Summary of Clinical Tests

Since the ACUSON Redwood Diagnostic Ultrasound Systems use the same technology and principles as existing predicate device, clinical studies were not required to support substantial equivalence.

UDFF Study Summary

Ultrasound-Derived Fat Fraction (UDFF) is a software tool that measures tissue in a selected region of interest and reports an index for assessing fat content in the liver. UDFF can be useful as an aid to a physician managing adult patients with hepatic steatosis.

The 5C1 transducer on the ACUSON Redwood Ultrasound System is compatible with the UDFF option. The UDFF feature in the ACUSON Redwood Ultrasound System (functionality, algorithms for UDFF measurements and calculations, implementation, etc.) is identical (remains unchanged) when compared to the UDFF feature in the reference device.

Two different studies were conducted to evaluate the performance of the UDFF feature on the ACUSON Redwood Ultrasound System. The demographic distribution of the study population in the two different studies are presented in the following table:

Study 1	**Study 2**
N= 30 subjects **Ethnicity/Country** USA = 15 Korea = 15 **Sex** Male = 15 Female = 15 **Age (years)** Mean ±SD = 41.1 ± 18.5 Range = 6 – 76 **BMI (kg/m^2)** Mean ± SD = 27.2 ± 6.8 Range = 11 – 44	N= 28 subjects **Ethnicity/Country** Korea = 28 **Sex** Male = 20 Female = 8 **Age (years)** Mean ±SD = 43.8 ± 18.0 Range = 19 – 74 **BMI (kg/m^2)** Mean ± SD = 27.2 ± 2.7 Range = 23 – 33

The study details and results are presented in the following table:

Study #	Study Objective	Evaluation Criteria	Results
1	To verify the correlation between the performance of the UDFF feature on ACUSON Redwood (subject device) and the UDFF feature on ACUSON Sequoia (reference device)	Significance level p-Value < 0.05 in a two-tailed test	Pearson Correlation coefficient between UDFF on ACUSON Redwood and ACUSON Sequoia was 0.98, and the difference is not statistically significant (p=0.792 and t-statistic = -0.263).
	To verify the clinical reliability of the UDFF feature on the ACUSON Redwood System	Test-retest ICC greater than 0.75	ICC = 0.98. The reliability of the UDFF feature on ACUSON Redwood is considered excellent.
	To record the UDFF measurement acquisition time	Exam time less than 60 seconds	All subjects acquisition time was within 22 seconds.
2	To verify that UDFF of ACUSON Redwood shows good agreement with MRI-PDFF	Absolute mean difference less than 5 percentage points and Bland-Altman limits of agreement within ±15 percentage points	Redwood UDFF and MRI's PDFF had Bland-Altman limits of agreement between -3.1 to 6.3 percentage points with a mean absolute difference of 1.59 percentage points.
	To verify the clinical accuracy of the ACUSON Redwood UDFF feature as compared to MRI- PDFF	AUROC greater than 0.80	Performance of UDFF on ACUSON Redwood showed strong performance as compared to MRI-PDFF with AUROC 0.85.

9. Summary

Intended uses and other key features of the subject device 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 systems have 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 the predicate device.