August 20, 2025

Siemens Medical Solutions USA, Inc.
Shilpa Rapaka
Senior Regulatory Affairs Specialist
22010 South East 51st Street
Issaquah, Washington 98029

Re: K251481
Trade/Device Name: ACUSON Sequoia Diagnostic Ultrasound System; ACUSON Sequoia Select Diagnostic Ultrasound System; ACUSON Origin Diagnostic Ultrasound System; ACUSON Origin ICE 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, QIH, OBJ
Dated: July 22, 2025
Received: July 22, 2025

Dear Shilpa Rapaka:

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,

Marjan Bakhtiari-nejad -S 2025.08.20 15:56:33 -04'00' For

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251481

Please provide the device trade name(s).

ACUSON Sequoia Diagnostic Ultrasound System;
ACUSON Sequoia Select Diagnostic Ultrasound System;
ACUSON Origin Diagnostic Ultrasound System;
ACUSON Origin ICE Diagnostic Ultrasound System

Please provide your Indications for Use below.

ACUSON Sequoia and Sequoia Select

The ACUSON Sequoia and Sequoia Select ultrasound imaging systems are 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, Neonatal Cephalic, Small Parts, OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures), Cardiac, Transesophageal, Pelvic, Vascular, Adult Cephalic, Musculoskeletal and Peripheral Vascular applications.

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

The system also provides the ability to measure anatomical structures for fetal, abdominal, pediatric, small organ, cardiac, transrectal, transvaginal, peripheral vessel, musculoskeletal 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
• 2D-mode with Harmonics Imaging
• 2D-mode with Harmonics Imaging for Contrast Agent Imaging
Color flow Doppler
• Color (velocity)
• Power (energy)
Doppler
• Pulsed Wave Doppler
• Pulsed Wave Doppler Tissue Imaging
• High Pulsed Repetition Frequency Pulsed Wave Doppler
• Steerable Continuous Wave Doppler for imaging transducers
• Continuous Wave Doppler for non-imaging transducers
M-mode
• M-mode with Harmonics Imaging
• Anatomical M-Mode
Elastography
• Strain Imaging
• Shear Wave Elastography
3D/4D Volume Imaging

Combined Modes

2D-mode with color
2D-mode with Doppler
2D-mode with color and Doppler
2D-mode with M-mode
2D-mode with M-mode and Color
2D-mode with Elastography
3D/4D Volume Imaging with color

ACUSON Origin and Origin ICE

The ACUSON Origin and Origin ICE ultrasound imaging systems are 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, OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures), Cardiac, Transesophageal, Intracardiac, Vascular, Adult Cephalic, and Peripheral Vascular applications.

The catheter is intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

The system also provides the ability to measure anatomical structures for fetal, abdominal, pediatric, cardiac, peripheral vessel, 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.

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• 2D-mode with Harmonics Imaging for Contrast Agent Imaging
Color flow Doppler
• Color (velocity)
• Power (energy)
Doppler
• Pulsed Wave Doppler
• Pulsed Wave Doppler Tissue Imaging
• High Pulsed Repetition Frequency Pulsed Wave Doppler
• Steerable Continuous Wave Doppler for imaging transducers
• Continuous Wave Doppler for non-imaging transducers
M-mode
• M-mode with Harmonics Imaging
• Anatomical M-Mode
3D/4D Volume Imaging

Combined Modes
2D-mode with color
2D-mode with Doppler
2D-mode with color and Doppler
2D-mode with M-mode
2D-mode with M-mode and Color
4D Volume Imaging with color

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

510(k) Summary

K251481

Date: July 22, 2025

1. Sponsor:

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

Contact Person:

Shilpa Rapaka
Regulatory Affairs Manager
+1 512-913-1053

2. Device Name:

ACUSON Sequoia Diagnostic Ultrasound System
ACUSON Sequoia Select Diagnostic Ultrasound System
ACUSON Origin Diagnostic Ultrasound System
ACUSON Origin ICE Diagnostic Ultrasound System

Common Name: Diagnostic Ultrasound System

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
Automated Radiological Image Processing Software	892.2050	QIH
Ultrasound Intravascular Catheter	892.1200	OBJ

Manufacturing Sites:

Siemens Medical Solutions USA, Inc.
22010 South East 51st Street, Issaquah, WA,
United States

Siemens Healthcare s.r.o.
Panattoni Park Kosice Airport ul. Andreja Kvasa 5 040 17, Kosice-Barca,
Slovakia

3. Legally Marketed Predicate Device

The ACUSON Sequoia, Sequoia Select, Origin, and Origin ICE Diagnostic Ultrasound Systems are multi-purpose, diagnostic ultrasound systems with accessories and proprietary software. They are substantially equivalent to the company's own products- ACUSON Sequoia, Sequoia Select, Origin, and Origin ICE (K242523).

Predicate Device: ACUSON Sequoia, Sequoia Select, Origin, and Origin ICE (K242523)

4. Device Description

The ACUSON Sequoia, Sequoia Select, Origin, and Origin ICE Diagnostic Ultrasound Systems (software version VC10) are multi-purpose, mobile, software-controlled, diagnostic ultrasound systems with an on-screen display of thermal and mechanical indices related to potential bio- effect mechanisms. The function of these ultrasound systems is to transmit, receive, process ultrasound echo data (distance and intensities information about body tissue) in various modes of operation and display it as ultrasound imaging, anatomical and quantitative measurements, calculations, analysis of the human body and fluid flow, etc. These ultrasound systems use a variety of transducers to provide imaging in all standard acquisition modes and also have comprehensive networking and DICOM capabilities.

5. Indications for Use

ACUSON Sequoia and ACUSON Sequoia Select

The ACUSON Sequoia and Sequoia Select ultrasound imaging systems are 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, Neonatal Cephalic, Small Parts, OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures), Cardiac, Pelvic, Vascular, Adult Cephalic, Musculoskeletal and Peripheral Vascular applications.

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  - 2D-mode with Harmonics Imaging for Contrast Agent Imaging
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  - Color (velocity)
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- Doppler
  - Pulsed Wave Doppler
  - Pulsed Wave Doppler Tissue Imaging
  - High Pulsed Repetition Frequency Pulsed Wave Doppler
  - Steerable Continuous Wave Doppler for imaging transducers
  - Continuous Wave Doppler for non-imaging transducers
- M-mode
  - M-mode with Harmonics Imaging
  - Anatomical M-mode
- Elastography
  - Strain Imaging
  - Shear Wave Elastography
- 3D/4D Volume Imaging
- Combined Modes
  - 2D-mode with color
  - 2D-mode with Doppler
  - 2D-mode with color and Doppler
  - 2D-mode with M-mode
  - 2D-mode with M-mode and Color
  - 2D-mode with Elastography
  - 3D/4D Volume Imaging with color

ACUSON Origin and Origin ICE

The ACUSON Origin and Origin ICE ultrasound imaging systems are 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, OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures), Cardiac, Transesophageal, Intracardiac, Vascular, Adult Cephalic, and Peripheral Vascular applications.

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  - High Pulsed Repetition Frequency Pulsed Wave Doppler
  - Steerable Continuous Wave Doppler for imaging transducers
  - Continuous Wave Doppler for non-imaging transducers
- M-mode
  - M-mode with Harmonics Imaging
  - Anatomical M-mode
- 3D/4D Volume Imaging
- Combined Modes
  - 2D-mode with color
  - 2D-mode with Doppler
  - 2D-mode with color and Doppler
  - 2D-mode with M-mode
  - 2D-mode with M-mode and Color
  - 4D Volume Imaging with color

6. Substantial Equivalence and Comparison of Technological Comparison to Predicates

The purpose of this Traditional 510(k) is to introduce the following improvements compared to the predicate device:

- Software feature enhancements and workflow improvements:

  - AI Measure and AI Assist workflow efficiency feature where the workflows are integrated such that, when cardiac view is classified, relevant AI Measure measurements labels (appropriate for the anatomy area or view detected by AI Assist) are automatically launched.
  - Liver Elastography optimization for all the abdominal shear wave elastography (SWE) modes- point shear wave elastography (pSWE), auto pSWE, and 2D SWE.
  - Ultrasound attenuation coefficient (Atten) was added to the ultrasound-derived fat fraction (UDFF) display, as an additional measurement.

- Calc feature improvements that include calculation of HC (Head Circumference) from BPD (Biparietal Diameter) and OFD (Occipital Frontal Diameter) and calculation of AC (Abdominal Circumference) from APAD (Anteroposterior Abdominal Diameter) and TAD (Transverse Abdominal Diameter).
- Heart rate measurement workflow enhancement that provides the users with the ability to enter Heart Rate value into the Measurement Display Area, which can be used for specific calculations, such as cardiac output. The subject devices support heart rate measurement entry from different modes with specific labels.
- Capture preview cardiovascular workflow improvement which allows the users to quickly review a captured clip and modify the capture length.
- A collection of workflow enhancements for General Imaging, Cardiovascular, Electrophysiology/ Intracardiac echocardiography.

- Transducer Imaging Quality improvements for the DAX and 8V3 transducers.

The intended use, indications for use, use environment, technological characteristics, acoustic output, software features, hardware, compatible transducers, safety, and effectiveness of the subject devices are substantially equivalent to the predicate device (K242523).

7. Nonclinical Data

The ACUSON Sequoia, Sequoia Select, Origin, and Origin ICE Diagnostic Ultrasound Systems comply with the following standards and guidance documents:

- 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 ES 60601-1:2005/(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, AMD2: 2021)
- 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
- IEC 62304: Medical Device Software – Software life cycle process, 2006 + A 2015
- ISO 13485:2016 Medical devices – Quality management systems- Requirements for regulatory purposes
- FDA Ultrasound Guidance document, "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers," issued in February 2023

Non-Clinical verification testing has been performed addressing system level requirements according to system and design specifications, and risk control measures. Design Control activities to assure the safety and effectiveness of the subject devices include but are not limited to the following:

- Requirements Review
- Risk Analysis and Risk Management
- Product Specifications
- Design Reviews
- Safety Testing
- Verification and Validation

8. Clinical Data

The proposed ACUSON Sequoia, Sequoia Select, Origin, and Origin ICE Diagnostic Ultrasound Systems did not require clinical studies to support substantial equivalence.

9. SWE Performance Testing

Phantom Testing

Verification testing for the Liver Elastography optimization was performed using calibrated elasticity phantoms certified by the phantom manufacturer. Table 1 lists the phantom stiffness range, SWE modes, and the supported transducers. The verification results met the acceptance criteria for accuracy and variability.

Table 1: Phantom Testing

Exam type	Phantom Stiffness range	Mode	DAX	5C1	9C2	4V1	10L4
Abdomen	3.0 - 75.0 kPa	pSWE	✓	✓	✓	✓	✓
		Auto pSWE	✓	-	✓	-	-
		2D SWE	✓	✓	✓	-	-

10. Summary

The subject and predicate devices are substantially equivalent in terms of intended use, indications for use, use environment, technological characteristics, acoustic output, software features, hardware, compatible transducers, safety, and effectiveness. For testing, all pre-determined acceptance criteria were met. Results of these tests show that the proposed subject devices continue to meet their intended use, and the modifications made do not raise new or different questions of safety and effectiveness in support of a substantially equivalence determination.