June 16, 2026

Siemens Medical Solutions USA, Inc.
Shilpa Rapaka
Regulatory Affairs Manager
22010 S. E. 51st St.
Issaquah, Washington 98029

Re: K260844
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, OBJ, QIH
Dated: May 20, 2026
Received: May 20, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Digitally signed by Michael D. O'hara -S
Date: 2026.06.16 15:10:02 -04'00'

Michael O'Hara, Ph.D.
Deputy Director
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.	K260844	?

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 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 (such as breast, testes, thyroid, penis prostate), 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, adult cephalic, 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:
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- Color (velocity)
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• Doppler
- Pulsed Wave Doppler
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- 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
• 3D/4D Volume Imaging with color

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

510(k) Summary

K260844

Date June 16, 2026

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

Primary Contact:
Shilpa Rapaka
Regulatory Affairs Manager
Phone: 512-913-1053

Secondary Contact:
Shan (Candice) Xue
Regulatory Affairs Specialist
Phone: 425-295-4286

2. Device Name(s):
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: 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 Ultrasonic Transducer	892.1570	ITX
Biopsy Needle Guide Kit	892.1560	OIJ
Ultrasound Intravascular Catheter	870.1200	OBJ
Automated Radiological Image Processing Software	892.2050	QIH

Manufacturing Sites: Siemens Medical Solutions USA, Inc.
22010 South East 51st Street, Issaquah, WA, USA 98029

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

3. Legally Marketed Predicate Devices

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

Predicate device: ACUSON Sequoia, Sequoia Select, Origin, and Origin ICE (K251481)

Reference device: ACUSON SC2000 (K233613)

4. Device Description

The ACUSON Sequoia, Sequoia Select, Origin, and Origin ICE Diagnostic Ultrasound Systems (software version VD10) are multi-purpose, mobile, software-controlled, diagnostic ultrasound systems. The systems provide an on-screen display of thermal and mechanical indices related to potential bioeffect mechanisms. The function of these ultrasound systems is to transmit, receive, and process ultrasound echo data (distance and intensity information about body tissue) using various modes of operation, and to display the data as ultrasound images, anatomical and quantitative measurements, calculations, analysis of the human body and fluid flow. These ultrasound systems support imaging with a variety of transducers across all standard acquisition modes and include comprehensive networking and DICOM capabilities.

5. Intended Use/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 (such as breast, testes, thyroid, penis prostate), 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.

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Combined Modes

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- 2D-mode with color and Doppler
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ACUSON Origin and Origin ICE

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6. Substantially Equivalent Devices and Summary of Technological Characteristics

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

- Introduction of the new Valves AI feature, an artificial intelligence based application for mitral, and aortic valve analysis. The feature creates models that illustrate valve anatomy and function and provides visualization and measurements of valvular motion for assessing valve health. This was previously cleared as eSie Valves on ACUSON SC2000 (K233613).
- Introduction of the new TrueFusion feature which shares real-time anatomical data with an angiography imaging system, enabling detection of the transducer position. This was previously cleared on ACUSON SC2000 (K233613).
- Enhancement of 2D Heart AI to include right side tracking. 2D Heart AI artificial intelligence based application was previously cleared on ACUSON Sequoia, Sequoia Select, Origin and Origin ICE (K251481) and provided automated contouring for all chambers but tracking workflow only for the left side.
- Quantitative Ultrasound (QUS) UDFF optimization on the 5C1 and 9C2 transducers to reduce measurement variability.
- Removal of legacy syngo framework from the software. Addition of Point Light Rendering Mode, Transparency Rendering Mode, Differential Tissue Harmonic Imaging (DTHI) for 2D B

Mode image quality Improvement, stress echo enhancements, high frame rate, volume imaging - 3D Freehand for the Origin models, optimization of backup and restore settings. All of these features are substantially equivalent to ACUSON Sequoia, Sequoia Select, Origin and Origin ICE (K251481).

- 7L2 transducer image quality improvement, which is substantially equivalent to ACUSON Sequoia, Sequoia Select, Origin and Origin ICE (K251481).
- Enablement of Contrast Enhanced Ultrasound (CEUS) on the Crystal catheters, Z6T and 5Z1 transducers , which is substantially equivalent to ACUSON Sequoia, Sequoia Select, Origin and Origin ICE (K251481).
- Update of accessories: DVD/CD Optical Drive update and addition of a new ECG Neonatal cable, which are substantially equivalent to ACUSON Sequoia, Sequoia Select, Origin and Origin ICE (K251481).

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 (K251481).

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:

- ANSI AAMI ES 60601-1:2005 + AMD2:2021, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1: 2005 + A1:2012 + A2: 2020 Edition 3.2, consolidated version, Medical electric equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 + A1: 2021, Edition 4.1, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 62359:2010 + AMD1:2017, Edition 2.1, Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields.
- IEC 60601-2-18: 2009, Edition 3.0, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- IEC 60601-2-37: 2024, Edition 3.0, 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: 2018, Fifth edition, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

- IEC 60601-1-6:2020, Edition 3.2, consolidated version, Medical Electrical Equipment Part 1-6, General Requirements for Basic Safety and Essential Performance- Collateral standard: Usability

- ANSI AAMI ISO 14971: 2019, Third Edition, Medical devices- Applications of risk management to medical devices

- IEC 62304: 2006 + A1 2015, Edition 1.1, consolidated version, Medical Device Software - Software life cycle process

- 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

Since the ACUSON Sequoia, Sequoia Select, Origin and Origin ICE Diagnostic Ultrasound Systems use the same technology and principles as existing predicate devices, clinical studies were not required to support substantial equivalence.

AI Study Summary for Valves AI

The overall accuracy (Mitral and Aortic valve) of the Valves AI algorithm with comparison of Valves AI with edits by the user compared to a reference auto-detection results on a verification dataset is explained by:

- Accuracy of Aortic and Mitral valve surface similarity and landmark distance errors meets acceptance criteria, with all metrics exceeding 80% at the lower bound of the 95% confidence interval.
- Pearson correlation coefficient of 0.9 or higher for measurements derived from surfaces and landmarks.

For subjects with a normal body mass index (BMI), the performance of the Valves AI algorithm was 0.97 or higher. For subjects with a BMI of >25 kg/m² (obese), performance was greater than 0.88.

Image datasets included the following parameters:

- 86 volumes were extracted from 42 studies at three different institutions
- Samples were acquired using the following transducers:
  - Z6T: 42 transesophageal echocardiogram (TEE) studies

Demographic distribution:

- Age: 35 to 93 years
- Gender: 44% female, 56% male
- Ethnicity/country: USA, Mexico

Known body mass index (BMI): 21 to 33

- 35% normal (BMI ≤25 kg/m²)
- 65% overweight/obese (BMI >25 kg/m²)

Reference Standard derivation/ truthing process:

- Three examiners created the reference standard by correcting the automatic valve detection using the editing tools available on the system.
- The reference standard consistency and reliability was quantified by assessing inter-user variability study where we observed a good correlation (with 0.9 and higher Pearson's coefficient) and low biases (lower than 10% in Bland-Altman analysis)

Independence of test data from training data:

- To ensure that the testing data is not mixed with the training data and is relevant, fresh data was collected for the verification purpose with most recent system and probes.

AI Study Summary for 2D Heart AI Enhancement

The accuracy of the 2D Heart^{AI} as measured by comparison of 2D Heart^{AI} with user edits compared to a reference standard ground truth on a dataset from five different institutions has

- Contour DICE average of 88%
- View classification performance with accuracy of 98% in average

For subjects with a Normal BMI the performance of the contouring AI Algorithm was 0.87 in average. For subjects with a BMI > 25 (obese), performance was 0.89 in average.

Image datasets included the following parameters:

The image dataset was collected from 48 patients from 5 institutions including different transducers (5V1, 5Z1, 8V3, 10V4), different views (Apical 2, 3, 4 chamber views) with frame rates greater than 17fps. Contrast was used in 10 exams. There were 96 images extracted from the 48 patients.

Demographic distribution:

- Age: Adults 1-83 years
- Gender: Female; 39%, Male; 61% (unknown: 63%)
- Ethnicity/Country: USA, Mexico
- BMI (known): 13 - 28
  73% Normal (BMI <= 25 kg/m2)
  27% Overweight + Obese (BMI > 25 kg/m2)

Reference Standard derivation/ truthing process:

- For all datasets, three examiners performed all manual contouring and measurements

Independence of test data from training data:

- To ensure that the testing data is not mixed with the training data and is relevant, fresh data was collected for the verification purpose with most recent system and probes.
- The reference standard consistency and reliability was quantified by assessing inter-user variability study where we observed a good correlation (with 0.9 and higher Pearson's coefficient) and low biases (around 10% in Bland-Altman analysis)

UDFF Performance Testing

Performance testing of UDFF was conducted using clinical data analysis to confirm that the 9C2 and 5C1 transducers meet requirements for clinical accuracy, reliability, and exam time. A 30-subject clinical study compared UDFF measurements from the 9C2 and 5C1 transducers to MRI-PDFF. Results showed reduced UDFF variability and improved agreement with MRI-PDFF.

9. 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.