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

July 22, 2024

Re: K240704
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 15, 2024
Received: July 15, 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.

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)*

K240704

Device Name

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

Indications for Use *(Describe)*

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: 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.

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
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

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.

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510(k) Summary

K240704

Date: July 10, 2024

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 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 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 Medical Solutions USA, Inc.
22010 South East 51st Street,

Issaquah, Washington 98029, UNITED STATES

3. Legally Marketed Predicate Devices and Reference Device

The ACUSON Sequoia, Sequoia Select, Origin and Origin ICE Diagnostic Ultrasound Systems are multi-purpose, diagnostic ultrasound systems with accessories and proprietary software, and are substantially equivalent to the company's own products- the ACUSON Sequoia, Sequoia Select, and Origin (K232145) which is the primary predicate device and the ACUSON SC2000 (K233613) as the reference device. And it is compatible with the reference device, AcuNav Crystal Ultrasound Catheter (K233270).

4. Device Description

The ACUSON Sequoia, Sequoia Select, Origin and Origin ICE Diagnostic Ultrasound Systems 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 ultrasound system 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, Panoramic Imaging, Contrast agent Imaging, Virtual Touch Strain Imaging (except Origin), Virtual Touch – pSWE Imaging, Virtual Touch – SWE Imaging, Custom Tissue Imaging, 3D/4D Volume Imaging or Harmonic Imaging on a Display and provide cardiac anatomical and quantitative function software applications.

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, OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures), Cardiac, 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
1. Strain Imaging
2. 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: 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.

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

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. Substantially Equivalent Devices and Summary of Technological Characteristics

The modified ACUSON Sequoia, Sequoia Select, Origin and Origin ICE Ultrasound Systems are based on the same system configuration as the company's own currently cleared ACUSON Sequoia and Sequoia Select (K232145) with regard to the intended use and technological characteristics. The ACUSON Sequoia, Sequoia Select, Origin and Origin ICE will have different software and transducer options for different markets. The ACUSON Sequoia, Sequoia Select, Origin and Origin ICE will offer an optional cardiac imaging and analysis package with new transducers and software applications

have been previously cleared by FDA under K232145 and not modified in the current submission. The modified ultrasound systems under this review and the predicate ultrasound systems function in the same manner as all diagnostic ultrasound systems and transducers.

The submission devices include following changes from predicate devices:

ACUSON Sequoia and Sequoia Select

- The modified ACUSON Sequoia and Sequoia Select Ultrasound System includes the expansion of the 'Pediatric' clinical application for UDFF (Ultrasonically-Derived fat fraction) which was already cleared on ACUSON Sequoia & Sequoia Select (K232145).
- Also this Traditional 510(k) includes 3D Data Converter (Exporting 3D Cartesian Data) and New Wi-Fi module which were cleared on the predicate device, ACUSON Sequoia & Sequoia Select (K232145) to enable an improved customer experience.

ACUSON Origin and Origin ICE

- Addition of two new catheters, AcuNav Crystal and SOUNDSTAR Crystal. Addition of the AcuNav Crystal and SOUNDSTAR Crystal Ultrasound Catheter compared to the predicate (K232145). The ACUSON Origin and Origin ICE Diagnostic Ultrasound Systems will be compatible with these two catheters for intracardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart.
- The additional model name, ACUSON Origin ICE. The proposed ACUSON Origin ICE system is substantially equivalent to ACUSON Origin (K232145) with regards to intended use, Indications for use, technological characteristics (Transducers, accessories and software features) and safety and effectiveness. All of technological characteristics are migrated (identical SW & HW platform) from the predicate device, ACUSON Origin (K232145), and there is no new feature or transducer compared to the predicate. Only the 5Z1 transducer is not supported or accessible for this model.
- Also this Traditional 510(k) includes CARTOSOUND, 3D Data Converter (Exporting 3D Cartesian Data) and New Wi-Fi module which were cleared on the predicate device, ACUSON Origin (K232145) and ACUSON SC2000 (K233613) to enable an improved customer experience.

All other hardware and software features of the ACUSON Sequoia, Sequoia Select, Origin and Origin IEC Diagnostic Ultrasound devices remain unchanged. The foundation of the ACUSON Sequoia, Sequoia Select, Origin and Origin ICE (this

submission) is the ACUSON Sequoia, Sequoia Select and Origin (K232145) with features and transducers integrated with the ACUSON Sequoia, Sequoia Select and Origin (K232145) hardware and the ACUSON Sequoia, Sequoia Select, Origin and Origin ICE (this submission) reuse software developed for Sequoia, Sequoia Select and Origin (K232145) mainly as well as AcuNav Crystal and SOUNDSTAR Crystal catheters from ACUSON SC2000 (K233613).

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

Performance testing summary for expansion of UDFF to pediatrics

- Summary of test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance

  - Clinical Accuracy:

  Criterion: UDFF measurements in children are considered to have acceptable correlation with MRI-PDFF, if the AUROC exceeds 0.80.

  - Results: our test results demonstrated that UDFF measurements in children have acceptable correlation with MRI-PDFF, with an AUROC ≥ 0.87.

  - Clinical Reliability:

  - Criterion: UDFF measurements in children are considered clinically reliable if the test-retest intraclass correlation coefficient (ICC) exceeds 0.75.
  - Results: our test results demonstrated that UDFF measurements in children had an ICC ≥ 0.97.

  - Exam Time:

  - Criterion: UDFF exam time in children is considered acceptable if it is under 60 seconds.
  - Results: our test results demonstrated that UDFF exam time is less than 60 seconds.

- The number of individual patients

- The studies included a total of 105 patients, with 40 patients scanned with the DAX transducer, 27 patients with the 5C1 transducer, and 38 patients with the 9C2 transducer.

- Data were collected from two institutions in the US and France.

- The number of samples, if different from above, and the relationship between the two

  - Five UDFF measurements were obtained per patient, resulting in a total of 525 measurements.

- Demographic distribution including Gender, Age, Ethnicity

  - Gender: Female; 23%, Male; 23%, Unknown; 54%

  - Age: 8 - 17 years

  - Ethnicity/Country: US, France

- Information about clinical subgroups and confounders present in the dataset

  - PDFF: 1.2% – 37%

    - 51% (PDFF <= 5%)
    - 49% (PDFF > 5%)

  - BMI: 14.2 – 47.9

    - 31% Normal (BMI <= 25 kg/m2)
    - 69% Overweight + Obese (BMI > 25 kg/m2)

- Information about equipment and protocols used to collect images

  - The UDFF measurements were acquired using the Sequoia ultrasound imaging systems in children undergoing clinically indicated MRI.

  - Three probes were used: DAX, 5C1, and 9C2.

  - Data were collected from two institutions

- Information about how the reference standard was derived from the dataset (i.e., the “truthing” process)

  - The new studies tested UDFF in children to expand its use to include both adults and children.

  - The UDFF algorithm remained unchanged and is the same for both adults and children. MRI PDFF was used as the reference standard, with steatosis defined as MRI PDFF greater than 5%.

- Description of how independence of test data from training data was ensured

  - The algorithm for UDFF was not retrained and remained unchanged.

- The dataset in these studies is considered test data to evaluate the performance of UDFF in children using MRI PDFF

8. Clinical Data

Since the ACUSON Sequoia, Sequoia Select, Origin and Origin ICE Diagnostic Ultrasound Systems use 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 Sequoia, Sequoia Select, Origin and Origin ICE systems are substantially equivalent with respect to safety and effectiveness of the primary predicate device.