February 6, 2023

Siemens Medical Solutions USA, Inc.
% Sulgue Choi
Regulatory Affairs Manager
22010 South East 51st Street
ISSAQUAH WA 98029

Re: K223735
Trade/Device Name: ACUSON Sequoia Diagnostic Ultrasound System, ACUSON Sequoia Select 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: December 13, 2022
Received: January 12, 2023

Dear Sulgue Choi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K223735

Device Name
ACUSON Sequoia Diagnostic Ultrasound System
ACUSON Sequoia Select Diagnostic Ultrasound System

Indications for Use *(Describe)*

The ACUSON Sequoia and Sequoia Select 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, 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 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

3D/4D Volume 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

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

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.***

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**510(k) Summary**

# K223735

**Date:** January 11, 2023

**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

**Common Name:** Diagnostic Ultrasound System with Accessories

**Classification:**

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

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

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

**3. Legally Marketed Predicate Devices**

The ACUSON Sequoia and Sequoia Select Diagnostic Ultrasound Systems are a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to the company's own products, the ACUSON Sequoia (K221500) which is primary predicated device.

- Primary Predicate Device: ACUSON Sequoia (K221500)

## 4. Device Description

The ACUSON Sequoia and Sequoia Select Diagnostic Ultrasound Systems are a multi-purpose mobile, software controlled, diagnostic ultrasound system with an on-screen display of thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to transmit and receive ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Color M Mode, Doppler Tissue Mode, Amplitude Doppler Mode, a combination of modes, Panoramic Imaging, Contrast agent Imaging, Virtual Touch Strain Imaging, Virtual Touch – pSWE Imaging, Virtual Touch – SWE Imaging, syngo Velocity Vector Imaging, Custom Tissue Imaging, 3D/4D Volume Imaging and Harmonic Imaging on a Display.

## 5. Intended Use/Indications for Use

The ACUSON Sequoia and Sequoia Select 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, 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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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

3D/4D Volume 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

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

**6. Summary of Technological Characteristics**

The modified ACUSON Sequoia and Sequoia Select Ultrasound Systems are the same as the company's own previously cleared ACUSON Sequoia (K221500) with regard to both intended use and technological characteristics. Both the modified ultrasound system under this review and the predicate ultrasound systems function in the same manner as all diagnostic ultrasound systems and transducers.

The submission device differs from the predicated devices as following:

- Software feature
  - The modified ACUSON Sequoia Ultrasound System includes the expansion of the UDFF (Ultrasonically-Derived fat fraction) software features for 5C1 transducer which were already cleared on the ACUSON Sequoia (K221500)

- Transducer & Accessories
  - The addition of needle guide kit, 10EV3, which is substantially equivalent to the needle guide Kit, 9EC4 previously cleared on the ACUSON Sequoia (K221500)

- Hardware change and improvement
  - New monitor and monitor arm
  - Common Control Panel and Control Panel cradle
  - Update rear storage basket

The foundation of the ACUSON Sequoia and Sequoia Select (this submission) are the ACUSON Sequoia(K221500) with features and transducers integrated with the ACUSON Sequoia(K221500) hardware and the ACUSON Sequoia and Sequoia Select(this submission) reuse software developed for Sequoia(K221500) mainly. All other hardware and software features of the ACUSON Sequoia and Sequoia Select Diagnostic Ultrasound devices remain unchanged.

The submission devices are substantially equivalent to the predicate with regards to both intended use and technological characteristics.

| Feature / Characteristic | ACUSON Sequoia This Submission | ACUSON Sequoia Select This Submission | ACUSON Sequoia K# 221500 Predicate device |
|---|---|---|---|
| **Indications for Use:** | | | |
| ▪ Fetal | √ | √ | √ |
| ▪ Abdominal | √ | √ | √ |
| ▪ Pediatric | √ | √ | √ |
| ▪ Small Organ | √ | √ | √ |
| ▪ Cardiac | √ | √ | √ |
| ▪ Transrectal | √ | √ | √ |
| ▪ Transvaginal | √ | √ | √ |
| ▪ Peripheral vessel | √ | √ | √ |
| ▪ Musculo-skeletal (conventional) | √ | √ | √ |
| ▪ Musculo-skeletal (superficial) | √ | √ | √ |
| ▪ Neonatal cephalic | √ | √ | √ |
| ▪ Adult cephalic | √ | √ | √ |
| **Frequencies Supported:** | √ (1.0MHZ~18MHz) | √ (1.0MHZ~18MHz) | √ (1.0MHZ~18MHz) |
| **Modes:** | | | |
| ▪ B | √ | √ | √ |
| ▪ M | √ | √ | √ |
| ▪ PWD (Pulsed Wave Doppler) | √ | √ | √ |
| ▪ CWD (Continuous Wave Doppler) | √ | √ | √ |
| ▪ PW DTI (Doppler Tissue Image) | √ | √ | √ |
| ▪ Color Doppler | √ | √ | √ |
| ▪ Power Doppler | √ | √ | √ |
| ▪ Combined (BMDC) | √ | √ | √ |
| **Features:** | | | |
| ▪ Harmonic imaging | √ | √ | √ |
| ▪ Panoramic imaging | √ | √ | √ |
| ▪ Color Panoramic imaging | √ | √ | √ |
| ▪ Auto TEQ | √ | √ | √ |
| ▪ Cardiac Imaging physiological signal display | √ | √ | √ |
| ▪ eSie OB | √ | √ | √ |
| ▪ Compounding | √ | √ | √ |
| ▪ Contrast imaging | √ | √ | √ |

| Feature / Characteristic | ACUSON Sequoia This Submission | ACUSON Sequoia Select This Submission | ACUSON Sequoia K# 221500 Predicate device |
|---|---|---|---|
| ▪ Clarify | √ | √ | √ |
| ▪ Virtual Touch - Strain | √ | √ | √ |
| ▪ syngo ® Velocity Vector Imaging | √ | √ | √ |
| ▪ eSie Calc | √ | √ | √ |
| ▪ Speed of Sound | √ | √ | √ |
| ▪ Fusion | √ | √ | √ |
| ▪ Virtual Touch – pSWE | √ | √ | √ |
| ▪ Virtual Touch – SWE | √ | √ | √ |
| ▪ UltraArt | √ | √ | √ |
| ▪ Modality Compare | √ | √ | √ |
| ▪ HD Zoom | √ | √ | √ |
| ▪ Protocols | √ | √ | √ |
| ▪ InFocus | √ | √ | √ |
| ▪ Flash sequencing | √ | √ | √ |
| ▪ Gesture control | √ | √ | √ |
| ▪ TeamViewer | √ | √ | √ |
| ▪ Motion Stabilized Persistence | √ | √ | √ |
| ▪ DICOM | √ | √ | √ |
| ▪ DICOM SR | √ | √ | √ |
| ▪ Slow Flow Color Doppler State | √ | √ | √ |
| ▪ Dynamic MultiHertz | √ | √ | √ |
| ▪ 3D/4D Volume Imaging Mode | √ | √ | √ |
| ▪ UDFF (Ultrasonically-Derived Fat Fraction) | √ | √ | √ |
| ▪ Auto pSWE | √ | √ | √ |
| ▪ Auto IMT | √ | √ | √ |
| ▪ eSieDoppler | √ | √ | √ |
| ▪ Virtual workstation | √ | √ | √ |
| ▪ Velocity Variance Mapping | √ | √ | √ |
| **Wireless** | √ | √ | √ |

| Feature / Characteristic | ACUSON Sequoia This Submission | ACUSON Sequoia Select This Submission | ACUSON Sequoia K# 221500 Predicate device |
|---|---|---|---|
| **Monitor: 21" FPD (OLED)** | √ (23.8" Dual Layer High Dynamic Range FPD) | √ (23.8" Dual Layer High Dynamic Range FPD) | √ |
| **Touch Screen: 15'' adjustable Touch Screen** | √ (13.3" adjustable touch screen) | √ (13.3" adjustable touch screen) | √ |
| **Output Display Standard (Track 3)** | √ | √ | √ |
| **Patient Contact Materials** | Tested to ISO 10993-1 | Tested to ISO 10993-1 | Tested to ISO 10993-1 |
| **UL 60601-1 Certified** | √ | √ | √ |
| **Indications for Use** | √ | √ | √ |

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

The 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)
- Safety and EMC Requirements for Medical Equipment
  - AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
  - IEC 60601-1:2005/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

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

Since the ACUSON Sequoia and Sequoia Select 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 and Sequoia Select systems are substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.