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

October 30, 2023

Re: K232145
Trade/Device Name: ACUSON Sequoia Diagnostic Ultrasound System, ACUSON Sequoia Select Diagnostic Ultrasound System, ACUSON Origin 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
Dated: July 18, 2023
Received: September 19, 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 (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

# Indications for Use

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

510(k) Number *(if known)*

**K232145**

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

Indications for Use *(Describe)*
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 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.

ACUSON Origin

The ACUSON Origin 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: 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.

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 colo

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.

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## 510(k) Summary K232145

**Date:** September 28, 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
ACUSON Origin 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 |
| Automated Radiological Image Processing Software | 892.2050 | 90-QIH |

**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, Sequoia Select, and Origin 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 and Sequoia Select (K223735) which is the primary predicate device and the ACUSON SC2000 (K211726) as the reference device.

## 4. Device Description

The ACUSON Sequoia, Sequoia Select, and Origin 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 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.

ACUSON Origin

The ACUSON Origin 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: 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.

**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. Substantially Equivalent Devices and Summary of Technological Characteristics

The modified ACUSON Sequoia, Sequoia Select, and Origin Ultrasound Systems are based on the same system configuration as the company's own currently cleared

ACUSON Sequoia and Sequoia Select (K223735) with regard to the intended use and technological characteristics. The ACUSON Sequoia, Sequoia Select, and Origin will have different software and transducer options for different markets. The ACUSON Sequoia, Sequoia Select, and Origin will offer an optional cardiac imaging and analysis package with new transducers and software applications with Artificial Intelligent algorithms. The ACUSON Sequoia, Sequoia Select, and Origin will offer four (4) new software applications (AI Measure, AI Assist, 2D Heart$^{AI}$, 4D Heart$^{AI}$) containing Machine Learning that are specifically intended to support cardiac imaging for blood flow, valves and anatomical features and modifies the Indications for Use. 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 addition of the Z6T transducer which is substantially equivalent to the Z6Ms transducer previously cleared on ACUSON SC2000 (K211726).
- The modified ACUSON Sequoia and Sequoia Select Ultrasound System includes the expansion of the 'transesophageal' clinical application which was already cleared on ACUSON SC2000 (K211726).
- Also this Traditional 510(k) includes additional new or improved imaging features and image quality improvement: Cardiac Volume Imaging Feature, AI Measure, AI 2D Heart, Stress Echo, and Wide FOV which were cleared on the predicate device, ACUSON Sequoia and Sequoia Select(K223735) and SC2000 (K211726) to enable an improved customer experience.

ACUSON Origin

- The addition of the Z6T transducer which is substantially equivalent to the Z6Ms transducer previously cleared on ACUSON SC2000 (K211726).
- The addition of the 5Z1 transducer which is substantially equivalent to the 4Z1c transducer previously cleared on ACUSON SC2000 (K211726).
- The addition of the AcuNav Lumos 4D ICE catheter which is substantially equivalent to the AcuNav Volume catheter previously cleared on ACUSON SC2000 (K211726).
- The modified ACUSON Origin Ultrasound System includes the expansion of the 'transesophageal' and 'intracardiac' clinical application which was already cleared on ACUSON SC2000 (K211726).
- Also this Traditional 510(k) includes additional new or improved imaging features and image quality improvement: Cardiac Volume Imaging Feature, AI Assist, AI Measure, 2D Heart$^{AI}$, Stress Echo, 4D Heart$^{AI}$, and Wide FOV which were cleared on the predicate device, ACUSON Sequoia and Sequoia Select (K223735) and SC2000 (K211726) to enable an improved customer experience.

All other hardware and software features of the ACUSON Sequoia, Sequoia Select, and Origin Diagnostic Ultrasound devices remain unchanged. The foundation of the ACUSON Sequoia, Sequoia Select, and Origin (this submission) is the ACUSON Sequoia and Sequoia Select (K223735) with features and transducers integrated with the ACUSON Sequoia and Sequoia Select (K223735) hardware and the ACUSON Sequoia, Sequoia Select, and Origin (this submission) reuse software developed for Sequoia and Sequoia Select (K223735) mainly as well as Z6T transducer, 5Z1 transducer, and Lumos 4D ICE catheter from ACUSON SC2000 (K211726).

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

| **Feature / Characteristic** | **ACUSON Sequoia This Submission** | **ACUSON Sequoia Select This Submission** | **ACUSON Origin This Submission** | **ACUSON Sequoia & Sequoia Select K# 223735 Predicate device** | **ACUSON SC2000 K# 211726 Predicate device** |
|---|---|---|---|---|---|
| **Indications for Use:** | | | | | |
| ▪ Fetal | √ | √ | -- | √ | √ |
| ▪ Abdominal | √ | √ | √ | √ | √ |
| ▪ Pediatric | √ | √ | √ | √ | √ |
| ▪ Small Organ | √ | √ | -- | √ | √ |
| ▪ OB/GYN | √ | √ | √ | √ | √ |
| ▪ Cardiac | √ | √ | √ | √ | √ |
| ▪ Transesophageal | √ | √ | √ | -- | √ |
| ▪ Intracardiac | -- | -- | √ | -- | √ |
| ▪ 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) | √ (1.0MHZ~18MHz) | √ (1.7MHZ~10MHz) |
| **Modes:** | | | | | |
| ▪ B | √ | √ | √ | √ | √ |

| Feature / Characteristic | ACUSON Sequoia This Submission | ACUSON Sequoia Select This Submission | ACUSON Origin This Submission | ACUSON Sequoia & Sequoia Select K# 223735 Predicate device | ACUSON SC2000 K# 211726 Predicate device |
|---|---|---|---|---|---|
| ▪ 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 | √ | √ | √ | √ | √ |
| ▪ Auto OB (eSie OB) | √ (Auto OB) | √ (Auto OB) | √ (Auto OB) | √ (eSie OB) | √ (eSie OB) |
| ▪ Compounding | √ | √ | √ | √ | √ |
| ▪ Contrast imaging | √ | √ | √ | √ | √ |
| ▪ Clarify | √ | √ | √ | √ | √ |
| ▪ Virtual Touch - Strain | √ | √ | -- | √ | √ |
| ▪ Auto Calcs (eSie Calcs) | √ (Auto Calcs) | √ (Auto Calcs) | √ (Auto Calcs) | √ (eSie Calcs) | √ (eie Calcs) |
| ▪ Speed of Sound | √ | √ | √ | √ | -- |
| ▪ Fusion | √ | √ | -- | √ | -- |
| ▪ Virtual Touch – pSWE | √ | √ | -- | √ | √ |
| ▪ Virtual Touch Auto pSWE | √ | √ | -- | √ | -- |

| Feature / Characteristic | ACUSON Sequoia This Submission | ACUSON Sequoia Select This Submission | ACUSON Origin This Submission | ACUSON Sequoia & Sequoia Select K# 223735 Predicate device | ACUSON SC2000 K# 211726 Predicate device |
|---|---|---|---|---|---|
| ▪ Virtual Touch – SWE | √ | √ | -- | √ | √ |
| ▪ UltraArt | √ | √ | √ | √ | -- |
| ▪ Modality Compare | √ | √ | √ | √ | -- |
| ▪ HD Zoom (Write Zoom) | √ | √ | √ | √ | -- |
| ▪ Workflow 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 IMT | √ | √ | √ | √ | √ |
| ▪ Auto Doppler (eSieDoppler) | √ (Auto Doppler) | √ (Auto Doppler) | √ (Auto Doppler) | √ (eSieDoppler) | √ (eSieDoppler) |
| ▪ Virtual workstation | √ | √ | √ | √ | -- |
| ▪ Velocity Variance Mapping | √ | √ | √ | √ | √ (Color dopper map) |

| Feature / Characteristic | ACUSON Sequoia This Submission | ACUSON Sequoia Select This Submission | ACUSON Origin This Submission | ACUSON Sequoia & Sequoia Select K# 223735 Predicate device | ACUSON SC2000 K# 211726 Predicate device |
|---|---|---|---|---|---|
| ▪ Cardiac Volume Imaging Feature | √ | √ | √ | -- | √ |
| ▪ AI Assist | √ | √ | √ | -- | -- |
| ▪ AI Measure | √ | √ | √ | -- | √ (eSie Measure) |
| ▪ 2D Heart[AI] | √ | √ | √ | -- | √ (Velocity Variance Mapping, eSie LH) |
| ▪ 4D Heart[AI] | -- | -- | √ | -- | √ (eSie LH, eSie LVA, eSie RH + GLS) |
| ▪ Stress Echo | √ | √ | √ | -- | √ |
| ▪ Wide FOV | √ | √ | √ | -- | -- |
| **Wireless** | √ | √ | √ | √ | √ |
| **Monitor: 23.8" Dual Layer High Dynamic Range FPD** | √ | √ | √ | √ | √ |
| **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 | Tested to ISO 10993-1 | Tested to ISO 10993-1 |
| **UL 60601-1 Certified** | √ | √ | √ | √ | √ |

## 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

AI Summary of Testing

AI Assist:

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

- AI Assist provides Color Box and Doppler Gate placement for 12 Cardiac Views and 1-4 anatomy locations in each view, for a total of 42 supported placements.
- Aggregating test results over all cardiac views and placement locations, the algorithm is successful 99.3% of the time. Successful placement means that no adjustment or only minor adjustment needs to be made by the user.
- As tested on datasets from different scanning views, the algorithm success is 92% or higher for any placement location.

- The number of individual patients' images were collected from
  - For AI Assist validation testing, image data was collected from 12 patients.

- The number of samples, if different from above, and the relationship between the two
  - For AI Assist validation testing, for each patient, data was collected for 12 cardiac views using either the 5V1 or the 5Z1 transducer. For two patients, additional data was collected for 12 cardiac views using the 8V3 transducer. 16 frames of data evenly spaced over 1 second are collected for each case.
  - This gives a total of 168 samples from 14 exams(12 patients). 72 samples use 5V1, 72 samples use 5Z1 and 24 samples use 8V3.

- Demographic distribution including Gender, Age, Ethnicity
  - Age: 18 – 81
  - Gender: Female; 17%, Male; 83%
  - Ethnicity/Country: US
  - BMI: 17.7 - 30.9
    58% Normal (BMI <= 25 kg/m2)
    42% Overweight / Obese (BMI > 25 kg/m2)

- Information about clinical subgroups and confounders present in the dataset
  - Test dataset include all 12 standard cardiac views supported with up to 4 anatomy areas supported by the AI Assist feature.

- Information about equipment and protocols used to collect images
  - The Origin platform was used to collect all data. The data collection was performed by a cardiac sonographer who scanned 12 cardiac views included in an Adult Echocardiogram examination.

- Information about how the reference standard was derived from the dataset (i.e., the "truthing" process)
  - For AI Assist verification of algorithms on the platform, expert cardiac sonographers provided "truth" by scoring the results of the AI Assist algorithm to assess success (no adjustment or minor adjustment needed) or failure (major adjustment needed). Three sonographers scored the results for each placement made by the algorithm.

- Description of how independence of test data from training data was ensured
  - Testing was performed on patient data completely independent from the data used in the model development processes. The patients were not associated with the sites where model development training data was collected.

2D Heart$^{AI}$

- Summary of test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance
  - 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 a Pearson correlation coefficient of 0.81 or higher with a minimal bias by Bland Altman of less than 5.2. For subjects with a Normal BMI the performance of the AI Algorithm was 0.84 or higher. For subjects with a BMI > 25 (Obese) performance was greater than 0.82.

- The number of individual patients' images were collected from
  - The image dataset was collected from 45 exams from 5 institutions including different transducers (5V1, 5Z1), different views (Apical 2, 3, 4 chamber views) with frame rates greater than 17fps. Contrast was used in 12 exams.

- The number of samples, if different from above, and the relationship between the two
  - There were 90 images extracted from the 45 exams.

- Demographic distribution including Gender, Age, Ethnicity

- Age: Adults 42-74 years
- Gender: Female; 24%, Male; 76%
- Ethnicity/Country: US, Mexico
- BMI: 18 - 36
  29% Normal (BMI <= 25 kg/m2)
  71% Overweight + Obese (BMI > 25 kg/m2)

- Information about clinical subgroups and confounders present in the dataset

  - During testing of the AI algorithm, we have included images from subjects with Normal and High BMI.

- Information about equipment and protocols used to collect images

  - The dataset consists of exams from across five institutions, two different probes (5V1, 5Z1) and different Origin Systems. The data collection protocol was standardized across all data collection sites.

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

  - For all datasets, three examiners perfomed all manual contouring and measurements. Variability was assessed by intraclass correlation (ICC), inter-reader variability was computed by using Pearson correlation and agreement (Bland-Altman). Reference standard for each measurement was established by calculating the mean value from the three examiners.

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

  - To ensure that the testing dataset is not mixed with the training data, we used datasets from different clinical sites for testing as compared to the clinical sites for training.

4D Heart$^{AI}$

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

  - The accuracy of the AI algorithm as measured by comparison of AI Algorithm with user edits compared to a reference standard ground truth on a dataset

from five different institutions has a Pearson correlation coefficient of 0.87 or higher with a minimal bias by Bland Altman of less than 13.3. For subjects with a Normal BMI the performance of the AI Algorithm was 0.98 or higher. For subjects with a BMI > 25 (Obese) performance was greater than 0.81.

- The number of individual patients' images were collected from

  - The image dataset was collected from 32 patients from 5 institutions including different transducers (5Z1 (17 TTE), 6ZT (15 TEE)), Volume rates were > 13.4vps.

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

  - There were 64 volumes were extracted from the 32 exams.

- Demographic distribution including Gender, Age, Ethnicity

  - Age: Adults 28-77 years
  - Gender: 68% Male, 32% Female
  - Ethnicity/Country: US, Mexico
  - BMI 21 - 34
    15% Normal (BMI <= 25 kg/m2)
    85% Overweight + Obese (BMI > 25 kg/m2)

- Information about clinical subgroups and confounders present in the dataset:

  - During testing of the AI algorithm, we have included images from subjects with Normal and High BMI.

- Information about equipment and protocols used to collect images:

  - The dataset was collected from across five institutions in the US and Mexico, two different probes (5Z1, 6ZT) and different Sequoia CV Systems. The data collection protocol was standardized across all data collection sites.

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

  - For all datasets, three examiners performed all manual contouring and measurements. Variability was assessed by intraclass correlation (ICC), inter-

reader variability was computed by using Pearson correlation and agreement (Bland-Altman). Reference standard for each measurement was established by calculating the mean value from the three examiners.

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

  - To ensure that the testing dataset is not mixed with the training data, we used datasets from different clinical sites for testing as compared to the clinical sites for training.

AI Measure

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

  - AI Measure covers a set of semi-automated cardiac measurements for Doppler, BMode and M-mode acquisitions.
  - Aggregating algorithm performance over all modes showed the AI algorithm was successful 89.6% based on acceptance of measurements as Pass or Pass with/Edit.
  - As tested on datasets from different aquisition modes, the algorithm sucess is 88.1% or higher

- The number of individual patients' images were collected from

  - The dataset was collected from 32 individual patients from 5 institutions

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

  - Overall 1354 samples were taken 392 images from 32 individual patients.

- Demographic distribution including Gender, Age, Ethnicity

  - Age: 4 - 79 years
  - Gender: Female; 44%, Male; 51%, Unknown; 5%
  - Ethnicity/Country: US, Mexico
  - BMI: 14 - 41.2
    49% Normal (BMI <= 25 kg/m2)
    51% Overweight + Obese (BMI > 25 kg/m2)

- Information about clinical subgroups and confounders present in the dataset
  - Test dataset includes all 15 measurement views from 3 acquisition modes (B-Mode, Doppler, M-Mode).

- Information about equipment and protocols used to collect images
  - The dataset consists of exams from across five institutions, five probes (5V1, 5Z1, 8V3, 10V4, Z6T) and different Sequoia CV Systems. The data collection protocol was standardized across all data collection sites.

- Information about how the reference standard was derived from the dataset (i.e., the “truthing” process)
  - For AI Measure verification of algorithms on the platform, expert cardiac sonographers provided “truth” by scoring the results of the AI Measure algorithm to assess success (measurements were deemed clinically acceptable). At least three sonographers scored the results for each measurement made by the algorithm.

- Description of how independence of test data from training data was ensured
  - To ensure that the testing dataset is not mixed with the training data, we used datasets from different clinical sites for testing as compared to the clinical sites for training.

## 8. Clinical Data

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