November 19, 2024

Siemens Medical Solutions USA, Inc.
Sulgue Choi
Regulatory Affairs Manager
22010 South East 51st Street
Issaquah, Washington 98029

Re: K242523
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: August 29, 2024
Received: October 28, 2024

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.

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,

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)*

K242523

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: 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.

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

K242523

Date: August 21, 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
Automated Radiological Image Processing Software	892.2050	QIH
Ultrasound Intravascular Catheter	892.1200	OBJ

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

Siemens Healthcare s.r.o.

Panattoni Park Kosice Airport ul. Andreja Kvasa 5 040 17,
Kosice-Barca, Slovakia

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, Origin and Origin ICE (K240704) which is the primary predicate device and the ACUSON Juniper and Juniper Select (K230207) as the reference device.

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: 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.

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, Sequoia Select, Origin and Origin ICE (K240704) 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 K240704 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 addition of the 11M2 transducer which is substantially equivalent to the 11M3 transducer previously cleared on ACUSON Sequoia, Sequoia Select, Origin, and Origin ICE (K240704).
- The addition of the HLX transducer which is substantially equivalent to the 15L4 and 18L6 transducer previously cleared on ACUSON Sequoia, Sequoia Select, Origin, and Origin ICE (K240704).
- The addition of needle guide kit, HLX, which is substantially equivalent to the needle guide Kit,16L4 previously cleared on the ACUSON Juniper (K230207)
- The modified ACUSON Sequoia and Sequoia Select Ultrasound System includes the expansion of the 5Z1 transduce, 4D Heart AI and AI Assist which was already cleared on ACUSON Sequoia, Sequoia Select, Origin, and Origin ICE (K240704).
- Also this Traditional 510(k) includes AI Abdomen which leverages AI Measure and AI Assist features released on the predicate ACUSON Origin (K240704), Trace AI which is an improvement of the generic eclipse measurement tool released on predicate ACUSON Origin (K240704), Needle Enhancement and Freehand 3D Volume Imaging which were cleared on the predicate device, ACUSON Sequoia, Sequoia Select, Origin, and Origin ICE (K240704) and ACUSON Juniper and Juniper Select (K230207) to enable an improved customer experience.

ACUSON Origin and Origin ICE

- The addition of the HLX transducer which is substantially equivalent to the 15L4 and 18L6 transducer previously cleared on ACUSON Sequoia, Sequoia Select, Origin, and Origin ICE (K240704).
- The addition of needle guide kit, HLX, which is substantially equivalent to the needle guide Kit, 16L4 previously cleared on the ACUSON Juniper (K230207)
- Also this Traditional 510(k) includes AI Abdomen which leverages AI Measure and AI Assist features released on the predicate ACUSON Origin (K240704), Trace AI which is an improvement of the generic eclipse measurement tool released on predicate ACUSON Origin (K240704) 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, Origin, and Origin ICE (K240704) with features and transducers integrated with the ACUSON Sequoia, Sequoia Select, Origin, and Origin ICE (K240704) hardware and the ACUSON Sequoia, Sequoia Select, Origin and Origin ICE (this submission) reuse software developed for Sequoia, Sequoia Select and Origin (K240704) mainly.

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

AI Summary of Testing

AI Abdomen

- Summary of test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance
  - AI Abdomen covers a set of semi-automated Abdomen view classifications and measurements for B-Mode acquisitions.
  - The algorithm achieved a success rate of 77.8% for view classification when aggregated across all 17 view types. When eliminating CBD and pancreas sagittal from the aggregated results, the accuracy increased to 82.5%.
  - For semi-automated measurements, the Individual Equivalence Coefficient (IEC) fell below the prespecified success criterion of 0.25 for all 12 measurements, with and without users editing the landmark locations.

- The number of individual patients' images were collected from
  - The dataset was consisted of 105 exams from 3 institutions collected on the following transducers: 4V1, 5C1, 9C2, 10L4, 11M2, 11M3, and DAX.

- The number of samples, if different from above, and the relationship between the two
  - A total of 1,785 images were extracted from the 105 exams, corresponding to the 17 abdomen views.

- Demographic distribution including Gender, Age, Ethnicity

- Age: 10 – 74 years
- Gender: Female; 57%, Male; 41%, Unknown; 2%
- Ethnicity/Country: US
- BMI: 16.3 – 47.3
  52% Normal (BMI <= 25 kg/m2)
  48% 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. The test datasets consist of 15 B-Mode images per view and per transducer.

- Information about equipment and protocols used to collect images
  - The dataset consists of exams from three institutions, seven probes (4V1, 5C1, 9C2, 10L4, 11M2, 11M3, DAX) and different Sequoia Systems. A system protocol was distributed to each data collection site to ensure standardization of the data collection process.

- Information about how the reference standard was derived from the dataset (i.e., the "truthing" process)
  - For view classification, the ground truth view label was associated with each image at the time of imaging using a system protocol.
  - Ground truth measurements were provided by three clinical users, all registered Clinical Sonographers with ARDMS accreditation (or equivalent), each with at least 3 years of clinical experience.

- 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.

Trace AI

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

- Trace AI is a semi-automated measurement tool that provides an ability to measure orifice-type anatomic structures on MPRs generated from volumetric ICE, TEE and TTE transducers.
- The accuracy goal is the 90th percentile shall have a minimum DICE coefficient of at least 80% with 90% confidence.
- The lower 90% confidence bound for the 90th percentile is 0.95, which is greater than the requirement of 0.8, therefore, the test passes.

- The number of individual patients' images were collected from

  - The testing data for our internal verification is from 10 different adult patients

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

  - 24 volumes were extracted from 10 exams.

- Demographic distribution including Gender, Age, Ethnicity
  - Age: 18 – 79 years
  - Gender: Female; 25%, Male; 62%, Unknown; 13%
  - Ethnicity/Country: US, Germany, Mexico
  - BMI: 18.1 – 44.2
    20% Normal (BMI <= 25 kg/m2)
    20% Overweight + Obese (BMI > 25 kg/m2)
    60% Unknown

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

  - The data used for testing captures a wide range of cardiac structures from different imaging transducers including 3D TEE, 3D TTE and 3D ICE. A total number of 24 samples were created during internal examinations, consisting of a variety of structures: left ventricle (LV), right ventricle (RV), left ventricle outflow tract (LVOT), left atrium (LA), ascending aorta (Asc Ao), mitral valve annulus (MV Annulus), ascending aorta sinotubular junction (Ao ST jnct.), left atrium appendage opening (LA App. Opening), sinus of valsalva (AO Sin. Vals.), tricuspid annulus (TV Ann). In summary, the test data are representative of the intended use population for Trace^{AI}.

- Information about equipment and protocols used to collect images:

  - The datasets were collected from three institutions in the US, Mexico and Germany. The testing data was collected using the Origin system at external

clinical sites. Transducers used include 5Z1 (3D TTE), Z6T (3D TEE) and Lumos (3D ICE).

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

  - Ground truth measurements were provided by three clinical users, all registered Clinical Sonographers with ARDMS accreditation (or equivalent), each with at least 3 years of clinical experience.

  - Each sonographer was given the same volume images with the same MPRs, the target orifice structures to delineate and which MPR the structure is located in (which avoids confusion when multiple orifice structures appear in the same MPR). Then each of the sonographers is asked to independently refine the initial circle given by Trace^{AI} to annotate the underlying orifice structure. During the process, sonographers can only see their own annotations and cannot see annotation results from other sonographers or a contour detected by Trace^{AI} algorithm. The contour created by sonographers (Ground Truth) is compared with the contour detected by Trace^{AI} (Detection Truth).

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

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

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.