Siemens Medical Solutions USA, Inc.
% Christine Dunbar
Senior Regulatory Affairs Specialist
685 East Middlefield Road
MOUNTAIN VIEW CA 94043

November 5, 2021

Re: K211726
Trade/Device Name: ACUSON SC2000 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, IYN, ITX, OBJ, LLZ
Dated: September 29, 2021
Received: October 4, 2021

Dear Christine Dunbar:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211726

Device Name
ACUSON SC2000 Diagnostic Ultrasound System

Indications for Use *(Describe)*

The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transesophageal, Adult Cephalic, Peripheral Vessel, Abdominal, Intraoperative Abdominal, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications. The system also provides the ability to measure anatomical structures 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.

The typical examinations performed using the SC2000 Ultrasound System are:

Cardiac Imaging Applications and Analysis

The system transmits ultrasound energy into adult, pediatric, neonatal, and fetal cardiac patients creating 2D (B), 3D, MMode (M), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave (PW) Doppler, and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the heart, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system also supports catheters which are intended for intra-cardiac and intraluminal 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 has Cardiac Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Vascular Imaging Applications and Analysis

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the carotid arteries or juggler veins in the neck; superficial and deep veins and arteries in the arms and legs and abdomen; and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images. The system has Vascular Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Superficial Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of conventional or superficial musculoskeletal structures and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

Intraoperative Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), and Pulsed Wave Doppler (PWD) to obtain images and blood flow velocity that provide guidance during intraoperative procedures.

Transcranial Imaging Applications

The system transmits ultrasound energy into the cranium of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the brain and surrounding anatomical structures to evaluate the presence or absence of pathology. The system provides Measurement Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

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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SECTION 1. 2. 510(K) SUMMARY - K211726

Date: **June 01, 2021 / September 28, 2021**

Part 1. Sponsor: Siemens Medical Solutions USA, Inc.,
Ultrasound Division
685 East Middlefield Road
Mountain View, California 94043

Contact Person: Christine Dunbar
Tel: (925) 374-2045

Part 2. Device Name: ACUSON SC2000 Diagnostic Ultrasound System - 21 CFR 807.92(a)(1)

Common Name: Diagnostic Ultrasound System with Accessories - 21 CFR 807.92(a)(2)

Classification: Regulatory Class: II
Review Category: Tier II
Classification Panel: 90, Radiology

Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Diagnostic Ultrasound Transducer	892.1570	90-ITX
Diagnostic Intravascular Catheter	892.1200	90-OBJ
Medical Image Management and Processing System (Optional for SC2000 Diagnostic US System)	892.2050	90-LLZ

Manufacturing Site: 22010 S. E. 51st Street, Issaquah, WA 98029, USA

Legal Manufacturer: Siemens Medical Solutions USA, Inc.
22010 S. E. 51st Street
Issaquah, WA 98029, USA

Part 3. Legally Marketed Predicate Devices - 21 CFR 807.92(a)(3)

The ACUSON SC2000 Diagnostic Ultrasound System is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to the company's own products, the ACUSON SC2000, v6.0 (VC10) under K202683 on October 15, 2021, is the primary predicate device.

The feature under modification is the *syngo*® TrueFusion 1.0 originally cleared under K171766 on July 12, 2017. The *syngo*® TrueFusion 1.0 software feature has been subsequently cleared under successive SC2000 Diagnostic Ultrasound device clearances including the most recent under K202683 as an optional feature. Therefore, K171766 serves as a reference predicate since Siemens prefers to continue

to clear the *syngo*® TrueFusion software as a software application on the SC2000 Diagnostic Ultrasound system device.

Part 4. Device Description - 21 CFR 807.92(a)(4)

The ACUSON SC2000 Diagnostic Ultrasound System is 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 and Harmonic Imaging on a Display. The transducer and catheter-based transducers will follow Track 3 acoustic labeling (AIUM 1004, IEC 2007, AIUM/NEMA 2004a).

Part 5. Intended Use and Indications for Use Statements - 21 CFR 807.92(a)(5)

SC2000 Diagnostic Ultrasound System, VC10 (v6.0)
(The Indications for Use remains unchanged as cleared under K202683 (VC10)

The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transesophageal, Adult Cephalic, Peripheral Vessel, Abdominal, Intraoperative Abdominal, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications. The system also provides the ability to measure anatomical structures 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.
The typical examinations performed using the SC2000 Ultrasound System are:

Cardiac Imaging Applications and Analysis
The system transmits ultrasound energy into adult, pediatric, neonatal, and fetal cardiac patients creating 2D (B), 3D, MMode (M), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave (PW) Doppler, and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the heart, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.
The system also supports catheters which are intended for intra-cardiac and intraluminal 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 system has Cardiac Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Vascular Imaging Applications and Analysis
The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the carotid arteries or juggler veins in the neck; superficial and deep veins and arteries in the arms and legs and abdomen; and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.
The system has Vascular Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Superficial Imaging Applications
The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of conventional or superficial musculoskeletal structures and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

Intraoperative Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), and Pulsed Wave Doppler (PWD) to obtain images and blood flow velocity that provide guidance during intraoperative procedures.

Transcranial Imaging Applications
The system transmits ultrasound energy into the cranium of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the brain and surrounding anatomical structures to evaluate the presence or absence of pathology.
The system provides Measurement Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Part 6. Summary of Technological Characteristics - 21 CFR 807.92(a)(6)

6.1 The ACUSON SC2000 VC11 (v6.1) Diagnostic Ultrasound System is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to the company's own products, the ACUSON SC2000 VC10 (v6.0) (K202683) with regard to both the intended use and technological characteristics. Both the subject ultrasound system and the predicate ultrasound system function in the same manner as similar diagnostic ultrasound systems and transducers including the cardiac catheters such as the ACUSON V and Volume ICE catheters and support for third party ICE catheters; the SoundStar™ 8F and 10F and the SoundStar™ *eco* 8F and *eco* 10F versions of the Diagnostic Ultrasound Catheters, which are developed, manufactured and distributed by Biosense Webster, Inc. under multiple clearances.

The *syngo*® TrueFusion 1.0 software feature that is currently cleared as an optional software application on the SC2000 Diagnostic Ultrasound system has remained essentially unchanged except for the minor modification to serial communications to support *Live Image Overlay* which is the combined imaging of the SC2000 Ultrasound system and Siemens-Healthineers Axios™ Fluoroscopy system imaging in real-time. The *syngo*® TrueFusion application software is comprised of the Siemens ACUSON SC2000 Diagnostic Ultrasound System used in conjunction with Siemens X-Ray Fluoroscopy systems called Artis™.

This new *Live Image Overlay* feature will be described in design descriptions for the *syngo*® TrueFusion 2.0 software feature.

The foundation of the ACUSON SC2000 VC11 (v6.1) with *syngo*® TrueFusion 2.0 software is the SC2000 VC10 (v6.0) release with *syngo*® TrueFusion 1.0 software. All other imaging features and transducers integrated with the ACUSON SC2000 Diagnostic Ultrasound system hardware and the software developed for SC2000 platform remain unchanged.

The SC2000 (WP) workplace system software includes the same currently cleared software applications supports the viewing of the *syngo*® TrueFusion acquired images, however the WP does not acquire Ultrasound images and is not present in the surgical / interventional suite.

It is Siemens' opinion that the ACUSON SC2000 VC11 (v6.1) is substantially equivalent to the predicate device, the ACUSON SC2000 VC10 (v6.0) with regards to both intended use, indications for use and technological characteristics.

6.2 - List of Technological Characteristics and SE Comparison Table

Feature / Characteristic	ACUSON SC2000 v6.1 Including Transducers, Catheters & *syngo*® TrueFusion 2.0 This Submission	ACUSON SC2000 6.0 K202683 Including Transducers AcuNav Volume ICE Catheter & 3rd Party Catheters & *syngo*® TrueFusion 1.0 option
Indications for Use:		
Indications for Use - Device	Unchanged for VC11 (v6.1)	√
▪ Fetal	√	√
▪ Abdominal	√	√
▪ Pediatric	√	√
▪ Small Organ	√	√
▪ **Cardiac**	√	√
▪ Peripheral vessel	√	√
▪ Musculo-skeletal (conventional)	√	√
▪ Musculo-skeletal (superficial)	√	√
Frequencies Supported:	√ (1.7MHz~10MHz)	√ (1.7MHz~10MHz)
Modes:	Unchanged for VC11 (v6.1)	
▪ B	√	√
▪ M	√	√
▪ PWD (Pulsed Wave Doppler)	√	√
▪ CWD (Continuous Wave Doppler)	√	√
▪ PW DTI (Doppler Tissue Image)	√	√
▪ Color Doppler	√	√
▪ Color Power Doppler (CPD)	√	√
▪ Combined (BMDC)	√	√
Transducers/ Catheters	Unchanged for VC11 (v6.1)	
Z6Ms - TEE Transducer	√	√
4Z1c - Phased Array Transducer	√	√
4Z1c - Phased Array Transducer – Imaging Preset update	√	√
10V4 - Phased Array Transducer	√	√
9L4 - Linear Array Transducer	√	√
9L4 - Linear Array Transducer – update imaging presat	√	√
4V1c - Phased Array Transducer	√	√
V5Ms - TEE Transducer	√	√
8V3 - Phased Array Transducer	√	√
V7M - TEE Transducer	√	√
6C1HD - Curved array transducer	√	√
CW2 - Continuous Wave Transducer	√	√
AcuNav 8F - Phased Array Ultrasound Catheter	√	√

Feature / Characteristic	ACUSON SC2000 v6.1 Including Transducers, Catheters & *syngo*® TrueFusion 2.0 This Submission	ACUSON SC2000 6.0 K202683 Including Transducers AcuNav Volume ICE Catheter & 3rd Party Catheters & *syngo*® TrueFusion 1.0 option
AcuNav 10F Intracardiac Transducer	√	√
AcuNav™ V ICE Catheter	√	√
AcuNav™ Volume ICE Catheter (aka P6)	√	√
AcuNav™ Volume ICE Catheter Imaging Preset update	√	√
Supports Third party US Catheters with Swift-Link connector:	√	√
SoundStar™ *eco* 8 French catheter[1]	√	√
SoundStar™ *eco* 10 French catheter	√	√
SoundStar™ 8 French catheter[2]	√	√
SoundStar™ 10 French catheter	√	√
SwiftLink Connector	√	√
Features on SC2000 System:	Unchanged for VC11 (v6.1)	
▪ Patient Registration Fields	√	√
▪ Change/Edit Patient Information Active exam	√	√
▪ Native™ tissue harmonic imaging (2D Brightness mode)	√	√
▪ TEQ™ ultrasound technology	√	√
▪ Volume ICE Package	√	√
▪ Support for AcuNav Volume ICE Catheter connected by SwiftLink cable.	√	√
▪ ICE Catheter Auto-reduce Mechanical Index (MI)	√	√
▪ 2D ICE Package	√	√

[1] SoundStar and SoundStar eco catheters are products of Biosense Webster, Inc. (A Johnson & Johnson company) holds the 510(k) clearances for these devices.
[2] SoundStar and SoundStar eco catheters are products of Biosense Webster, Inc. (A Johnson & Johnson company) holds the 510(k) clearances for these devices.

Feature / Characteristic	ACUSON SC2000 v6.1 Including Transducers, Catheters & *syngo*® TrueFusion 2.0 This Submission	ACUSON SC2000 6.0 K202683 Including Transducers AcuNav Volume ICE Catheter & 3rd Party Catheters & *syngo*® TrueFusion 1.0 option
▪ True Volume Imaging Support, AcuNav Volume ICE Catheter	√	√
▪ Volume Color Doppler	√	√
▪ Fetal Echo Calculations	√	√
▪ Fetal Imaging Presets	√	√
▪ Cardiac Imaging physiological signal display	√	√
▪ eSie Measure on TEE	√	√
▪ Advanced SieClear™ spatial compounding	√	√
▪ Clarify™ vascular enhancement technology	√	√
▪ syngo ® Velocity Vector Imaging (eSie VVI)	√	√
▪ syngo ® Velocity Vector Imaging (eSie VVI)	Changed to be consistent with v5.1 implementation.	√
▪ eSie Valves Advanced Measurement Package	√	√
▪ eSie LVA: 5 Cardiac Cycles	√	√
▪ eSie PISA	√	√
▪ eSie Left Heart Measurement Package	√	√
▪ Volume Right Ventricular Analysis (RVA)	√	√
▪ Stress Echo Package	√	√
▪ Rapid Stress Volume Stress Echo App.	√	√
▪ Cardiac Measurements and Calculations	√	√
▪ syngo ® TrueFusion v1.0	√	√
▪ syngo ® TrueFusion v2.0	Updated to support Live Imaging Overlay	TrueFusion 1.0
▪ syngo ® TrueFusion v2.0	Update communication protocol for True Fusion 2.0.	TrueFusion 1.0
▪ Septal Guide – Orthogonal Guidelines	√	√
▪ VR Measurement Tools (Volume)	√	√
▪ Reference Lines ▪ One-click MPR alignment	√	√

Feature / Characteristic	ACUSON SC2000 v6.1 Including Transducers, Catheters & *syngo*® TrueFusion 2.0 This Submission	ACUSON SC2000 6.0 K202683 Including Transducers AcuNav Volume ICE Catheter & 3rd Party Catheters & *syngo*® TrueFusion 1.0 option
▪ Volume Reference Line Projections ▪ eSie Slice / eSie Lines	√	√
▪ One-click MPR A/B Align on Volume Review (VR)	√	√
▪ Trace erase, back up behavior with Trackball: B-Mode	√	√
▪ Single V	√	√
▪ Contrast Agent Imaging LVO	√	√
▪ Edit patient data on active exam.	√	√
▪ Zoom & Pan	√	√
▪ eSieScan (Protocols)	√	√
▪ InFocus Coherent Technology	√	√
▪ Circle Tool	√	√
▪ DICOM ▪ DICOM SR (Structure Reports)	√ √	√ √
▪ DICOM GSDF (Gray scale Standard Display Function).	√	√
▪ DICOM Tags (Teamplay) ▪ DICOM support the export of DICOM tags for System Data Collection	√	√
MS Windows 10 OS	**Windows 10 plus updates**	Windows 10
Wireless - enabled	√	√
WiFi EAP-TLS authentication protocol	√	√
Cybersecurity Features	√	√
Security – User Accounts User Accounts \\local user authentication	√	√
Table Side Remote Control Joy-Stick	√	√
Service Save logs	√	√
Service Save logs	include save log location	Service Logs available

Feature / Characteristic	ACUSON SC2000 v6.1 Including Transducers, Catheters & *syngo*® TrueFusion 2.0 This Submission	ACUSON SC2000 6.0 K202683 Including Transducers AcuNav Volume ICE Catheter & 3rd Party Catheters & *syngo*® TrueFusion 1.0 option
Security Hot-fix Installation	install a hotfix update via RUH (remote update handling) or USB drive.	install a hotfix update via RUH (remote update handling) or USB drive.
Study Back-up and Restore	√	√
Monitor: 21" FPD	√	√
Output Display Standard (Track 3)	√	√
Patient Contact Materials	Tested to ISO 10993-1	Tested to ISO 10993-1
UL 60601-1 Certified	√	√

Part 7. A brief discussion of nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. 21 CFR 807.92(b)(1)

The device has 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 SC2000 software update to VC11 (v6.1) does not involve any hardware modifications. The VC11A (v6.1) software update and the SC2000 System software has undergone component, integration and system level verification testing. The software verification and regression testing has been performed successfully to meet their previously determined acceptance criteria consistent with Siemens Product Lifecycle Procedure (PLP) and has passed. The ACUSON SC2000 Ultrasound system complies with the following standards:

- AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
  IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2: 2007(Third Edition), Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-2-37:2007+A1:2015, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasound medical diagnostic and monitoring equipment
- IEC 60601-2-18:2009, Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment
- IEC 62304:2006 Medical Device Software – Software Life Cycle Processes
- AIUM/NEMA UD-3:2004, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2:2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- ISO 10993-1:2009, Biological evaluation of Biological evaluation of Medical Devices
- IEC 62366:2014, Medical Devices – Application of Usability
- IEC 62359:2010, Ultrasonics – Field characterization – Test Methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields.

Part 8. A summary discussion of the clinical tests submitted, referenced, or relied on for a determination of substantial equivalence. 21 CFR 807.92(b)(2)

Since the ACUSON SC2000 VC11 (v6.1) Diagnostic Ultrasound System uses the identical technology and principles of use as the existing predicate devices SC2000, VC10 (v6.0) K202683, clinical studies were not required to support substantial equivalence. The SC2000 VC11A (v6.1) software was fully validated on phantoms by clinical personal with training in Ultrasound technology and has passed.

Substantial Equivalence to Predicates (21 CFR §807.92(b)(1))

The verification testing to the Customer requirements (CRS) for the SC2000 Diagnostic Ultrasound System including component, integration and regression testing for TrueFusion 2.0 and validation of the intended use is intended to support the claim of substantial equivalence to the following predicates:

> The ACUSON SC2000, v6.0 (VC10) under K202683 on October 15, 2021, is the primary predicate device. The VC10 software includes the syngo® TrueFusion 1.0 software feature as an option.

> The feature under modification is the syngo® TrueFusion 1.0 which was originally cleared under K171766 on July 12, 2017, this clearance serves as a reference predicate.

Part 9. Summary - 21 CFR 807.92(b)(3)

The 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. The SC2000 Diagnostic ultrasound systems have accumulated a long history of safe and effective performance.

In summary, based on the successful verification and validation testing to the software acceptance criteria, the update for the TrueFusion 2.0 feature does not introduce any new potential safety risks. It is the opinion of Siemens Medical Solutions USA, Inc. that the ACUSON SC2000 Diagnostic Ultrasound system with the VC11 (v6.1) software update is substantially equivalent with respect to safety and effectiveness and performs as well as the currently cleared predicate device.