June 12, 2024

Siemens Medical Solutions USA, Inc.
Shilpa Rapaka
Senior Regulatory Affairs Specialist
22010 South East 51st Street
ISSAQUAH WA 98029

Re: K233613
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: May 31, 2024
Received: May 31, 2024

Dear Shilpa Rapaka:

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

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

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

Sincerely,

Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233613

Device Name

ACUSON SC2000 Diagnostic Ultrasound System

Indications for Use *(Describe)*

The ACUSON SC2000 Diagnostic Ultrasound 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: 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 ACUSON SC2000 Diagnostic 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, M-Mode (M), 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 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.
Catheters are 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 jugular veins in the neck; superficial and deep veins and arteries in the arms and legs; superficial and deep veins and arteries in the 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.

Operating Modes

Single Modes
• Volume imaging
• Thin volume imaging
• 2D mode
• M-mode
• Pulsed wave Doppler
• Continuous wave Doppler
• Native Tissue Harmonic Imaging (NTHI)
• Auxiliary continuous wave Doppler
• Color Doppler Velocity (CDV)
• Color Doppler Energy (CDE)
• Doppler Tissue Energy (DTE)
• Doppler Tissue Velocity (DTV)
• Left Ventricular Opacification (LVO)

Combined Modes
• 2D/M-mode
• 2D/M-mode with Color Doppler
• 2D/pulsed wave Doppler
• 2D/pulsed wave Doppler with Color Doppler
• 2D/continuous wave Doppler
• 2D/continuous wave Doppler with Color Doppler
• 2D/Color Doppler
• Thin volume/Color Doppler
• Volume imaging/Color Doppler

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

K233613

Date: May 30, 2024

1. Sponsor:
Siemens Medical Solutions USA, Inc.
Ultrasound Division
22010 South East 51st Street
Issaquah, WA 98029, USA

Contact Person:
Shilpa Rapaka
Senior Regulatory Affairs Specialist
Phone: 512-913-1053

2. Device Name: ACUSON SC2000 Diagnostic Ultrasound System

Common Name: Diagnostic Ultrasound System

Classification:
Regulatory Class: II
Classification Panel: Radiology

Classification Name	21 CFR Section	Product Code
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Diagnostic Ultrasound Transducer	892.1570	ITX
Ultrasound Intravascular Catheter	870.1200	OBJ
Radiological Image Processing System	892.2050	LLZ

Manufacturing Site:
Siemens Medical Solutions USA, Inc.
Ultrasound Division
22010 South East 51st Street
Issaquah, WA 98029, USA

3. Legally Marketed Predicate Device and Reference Devices

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. It is substantially equivalent to the company's own product, the ACUSON SC2000 Diagnostic Ultrasound System v6.1 (VC11) cleared under K211726 and is compatible with the reference devices, AcuNav Crystal Ultrasound Catheter (K233270) and SoundStar Crystal Ultrasound Catheter (K240050).

Predicate Device: ACUSON SC2000 Diagnostic Ultrasound System (K211726)

Reference Devices: AcuNav Crystal Ultrasound Catheter (K233270) and SoundStar Crystal Ultrasound Catheter (K240050)

4. Device Description

The ACUSON SC2000 Diagnostic Ultrasound System is a multi-purpose diagnostic ultrasound system with proprietary software and accessories. The function of the ACUSON SC2000 Diagnostic Ultrasound System is to transmit, receive, process ultrasound echo data (distance and intensities information about body tissue) in various modes of operation and display it as ultrasound imaging, measurements, calculations, analysis of the human body and fluid flow, etc.

5. Indications for Use

The ACUSON SC2000 Diagnostic Ultrasound 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: 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.

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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.

Catheters are 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 jugular veins in the neck; superficial and deep veins and arteries in the arms and legs; superficial and deep veins and arteries in the 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.

Operating Modes

Single Modes

- Volume Imaging
- Thin Volume imaging
- 2D-mode
- M-mode
- Pulsed Wave Doppler
- Continuous Wave Doppler
- Native Tissue Harmonic Imaging (NTHI)
- Auxiliary Continuous Wave Doppler
- Color Doppler Velocity (CDV)
- Color Doppler Energy (CDE)
- Doppler Tissue Energy (DTE)
- Doppler Tissue Velocity (DTV)
- Left Ventricular Opacification (LVO)

Combined Modes

- 2D/M-mode

- 2D/M-mode with Color Doppler
- 2D/Pulsed Wave Doppler
- 2D/Pulsed Wave Doppler with Color Doppler
- 2D/Continuous Wave Doppler
- 2D/Continuous Wave Doppler with Color Doppler
- 2D/Color Doppler
- Thin volume/Color Doppler
- Volume imaging/Color Doppler

6. Substantially Equivalent Devices and Comparison of Technological Characteristics

The purpose of this submission is to introduce the AcuNav Crystal Ultrasound Catheter (K233270), the SoundStar Crystal Ultrasound Catheter (K240050), and SwiftLink Plus Connector as being compatible with the ACUSON SC2000 Diagnostic Ultrasound System v6.5 (VC15). The AcuNav Crystal Ultrasound Catheter and the SoundStar Crystal Ultrasound Catheter are sterile, single-use, disposable imaging catheters. These catheters are for intracardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. These catheters have been tested and found to be compatible with the ACUSON SC2000 Diagnostic Ultrasound System v6.5 (VC15).

The SwiftLink Plus Connector is a port adapter cable that connects the AcuNav Crystal Ultrasound Catheter and the SoundStar Crystal Ultrasound Catheter to the ACUSON SC2000 Diagnostic Ultrasound System v6.5. SwiftLink Plus connector is substantially equivalent to the SwiftLink connector previously cleared on the predicate device ACUSON SC2000 v6.1 (VC11)- K211726.

The intended use, indications for use, use environment, technological characteristics, software features, hardware, safety, and effectiveness of the subject device are substantially equivalent to the predicate device (K211726).

7. Nonclinical Data

The ACUSON SC2000 Diagnostic Ultrasound Systems comply with the following voluntary standards:

- IEC 62359:2010 /A1(2017), Ultrasonic- Field characterization- Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic field / This document and its separate amendments continue to be valid together with the consolidation version
- AAMI ES 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) and AMD2: 2021 Medical electrical equipment- Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, AMD2: 2021)
- IEC 60601-1:2005/A1(2012)/A2(2020) (Ed. 3.2), 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: 2014/A1(2020), 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
- IEC 62304: Medical Device Software – Software life cycle process, 2006 + A 2015
- ISO 13485:2016 Medical devices – Quality management systems- Requirements for regulatory purposes
- FDA Ultrasound Guidance Document titled *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* issued on February 21, 2023 (https://www.fda.gov/media/71100/download) for determining measurement accuracy

8. Clinical Data

The proposed ACUSON SC2000 Diagnostic Ultrasound System did not require clinical studies to support substantial equivalence.

9. Summary

The subject and predicate device are substantially equivalent in terms of intended use, indications for use, use environment, technological characteristics, software features, hardware, safety, and effectiveness. The non-clinical testing data support the safety of the device and demonstrate that the ACUSON SC2000 Diagnostic Ultrasound System is compatible with the AcuNav Crystal Ultrasound Catheter and the SoundStar Crystal Ultrasound Catheter and the system performs as intended in the specified use conditions. Therefore, it is the opinion of Siemens Medical Solutions USA, Inc. that the ACUSON SC2000 Diagnostic Ultrasound Systems are as safe and effective with substantially equivalent performance as the predicate device.