June 12, 2024

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

Re: K233610
Trade/Device Name: ACUSON P500 Ultrasound System; ACUSON P500 ICE Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, OBJ, OIJ
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)*

K233610

Device Name

ACUSON P500 Ultrasound System;
ACUSON P500 ICE Ultrasound System

Indications for Use *(Describe)*

ACUSON P500 Ultrasound System
The ACUSON P500 ultrasound imaging system is intended to provide images of, or signals from, inside the body by an appropriately trained healthcare professional in a clinical setting for the following applications: Fetal, Abdominal (including liver), Pediatric, Small Parts, Transcranial, Transesophageal, OB/GYN (useful for visualization of ovaries, follicles, uterus and other pelvic structures), Lung, Pelvic, Neonatal Cephalic, Cardiac, Intra Cardiac, Vascular (including Peripheral Vessel), Musculoskeletal, Superficial Musculoskeletal and Urology 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 Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system.

ACUSON P500 ICE Ultrasound System
The ACUSON P500 ICE ultrasound imaging system is intended to provide images of, or signals from, inside the body by an appropriately trained healthcare professional in a clinical setting for the following applications: Fetal, Abdominal (including liver), Pediatric, Small Parts, Transcranial, Transesophageal, OB/GYN (useful for visualization of ovaries, follicles, uterus and other pelvic structures), Lung, Pelvic, Neonatal Cephalic, Cardiac, Intra Cardiac, Vascular (including Peripheral Vessel), Musculoskeletal, Superficial Musculoskeletal and Urology 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 Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system.

Operating Modes
- 2D-Mode
  - o 2D-Mode with Harmonics Imaging
- Color flow Doppler
  - o Color (Velocity)1
  - o Power (Energy)2
  - o Doppler Tissue Imaging
- Pulsed Wave Doppler
  - o Pulsed Wave Doppler Tissue Imaging

o High Pulsed Repetition Frequency Pulsed Wave Doppler
• Continuous Wave Doppler
o Steerable Continuous Wave Doppler for phased array transducers
o Auxiliary Continuous Wave Doppler for pencil transducers
• M-Mode
o M-Mode with Harmonics Imaging
o Anatomical M-Mode

1Color is also known as Color Doppler Velocity (CDV).
2Power is also known as Color Doppler Energy (CDE).

Combined Modes
• 2D-Mode with Color
• 2D-Mode with Power
• 2D/Doppler
• 2D/Doppler with Color
• 2D/Doppler with power
• 2D/M-mode
• 2D/M-mode with Color
• 2D/Anatomical M-mode

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

K233610

Date: May 31, 2024

1. Sponsor:

Siemens Medical Solutions USA, Inc.
Ultrasound Division
22010 South East 51st Street
Issaquah, Washington 98029

Contact Person: Shilpa Rapaka
Tel: +1 (512) 913-1053

Secondary Contact: SeongMin Han
Tel: +82 10 4697 8360

2. Device Name: ACUSON P500 Ultrasound System
ACUSON P500 ICE Ultrasound System

Common Name: Diagnostic Ultrasound System with Accessories

Classification: Regulatory Class: II
Classification Panel: Radiology

Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX
Diagnostic Intravascular Catheter	870.1200	OBJ
Biopsy Needle Guide Kit	892.1560	OIJ

Manufacturing Site: Siemens Healthcare s.r.o.
Panattoni Park Kosice Airport ul.
Andreja Kvasa 5 040 17, Kosice-Barca, Slovakia

3. Legally Marketed Predicate Devices

The ACUSON P500 and P500 ICE Ultrasound Systems v3.1 (VC11) are multi-purpose diagnostic ultrasound systems with accessories and proprietary software and are substantially equivalent to the company's own product, the ACUSON P500 (K213487) v3.0 (VC10) which is the predicate device. And the company's own product, AcuNav Crystal Ultrasound Catheter (K233270) is the Reference device which is compatible to ACUSON P500 and P500 ICE Ultrasound Systems v3.1 (VC11).

- Predicate Device: ACUSON P500 (K213487)
- Reference Device: AcuNav Crystal Ultrasound Catheter (K233270)
- Reference Device: SoundStar Crystal Ultrasound Catheter (K240050)

4. Device Description

The ACUSON P500 and P500 ICE 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. 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, Power(Amplitude) Doppler Mode, a combination of modes and Harmonic Imaging on a Display.

5. Intended Use/Indications for Use

ACUSON P500 Ultrasound System

The ACUSON P500 ultrasound imaging system is intended to provide images of, or signals from, inside the body by an appropriately trained healthcare professional in a clinical setting for the following applications: Fetal, Abdominal (including liver), Pediatric, Small Parts, Transcranial, Transesophageal, OB/GYN (useful for visualization of ovaries, follicles, uterus and other pelvic structures), Lung, Pelvic, Neonatal Cephalic, Cardiac, Intra Cardiac, Vascular (including Peripheral Vessel), Musculoskeletal, Superficial Musculoskeletal and Urology 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 Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system.

ACUSON P500 ICE Ultrasound System

The ACUSON P500 ICE ultrasound imaging system is intended to provide images of, or signals from, inside the body by an appropriately trained healthcare professional in a clinical setting for the following applications: Fetal, Abdominal (including liver), Pediatric, Small Parts, Transcranial, Transesophageal, OB/GYN (useful for visualization of ovaries, follicles, uterus and other pelvic structures), Lung, Pelvic, Neonatal Cephalic, Cardiac, Intra Cardiac, Vascular (including Peripheral Vessel), Musculoskeletal, Superficial Musculoskeletal and Urology applications.
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The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system.

Operating Modes

- 2D-Mode
    - 2D-Mode with Harmonics Imaging

- Color flow Doppler
  - Color (Velocity)[1]
  - Power (Energy)[2]
  - Doppler Tissue Imaging
- Pulsed Wave Doppler
  - Pulsed Wave Doppler Tissue Imaging
  - High Pulsed Repetition Frequency Pulsed Wave Doppler
- Continuous Wave Doppler
  - Steerable Continuous Wave Doppler for phased array transducers
  - Auxiliary Continuous Wave Doppler for pencil transducers
- M-Mode
  - M-Mode with Harmonics Imaging
  - Anatomical M-Mode

[1]Color is also known as Color Doppler Velocity (CDV).
[2]Power is also known as Color Doppler Energy (CDE).

Combined Modes
- 2D-Mode with Color
- 2D-Mode with Power
- 2D/Doppler
- 2D/Doppler with Color
- 2D/Doppler with power
- 2D/M-mode
- 2D/M-mode with Color
- 2D/Anatomical M-mode

6. Substantially Equivalent Devices and Summary of Technological Characteristics

The modified ACUSON P500 and P500 ICE Ultrasound Systems are the same as the company's own previously cleared ACUSON P500 (K213487) with regard to both intended use and technological characteristics. Both the modified ultrasound systems under this review and the predicate ultrasound system function in the same manner as all diagnostic ultrasound systems and transducers.

The submission device differs from the predicated devices as following:

- Transducer & Accessories
  - The modified ACUSON P500 and P500 ICE Ultrasound Systems include the addition of AcuNav Crystal Ultrasound Catheter, SoundStar Crystal Ultrasound Catheter, and SwiftLink Plus connector. ACUSON P500 and P500 ICE are compatible with this next generation ICE catheters for intracardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart.
    This AcuNav Crystal Ultrasound Catheter was cleared on 510(k) K233270.

    This SoundStar Crystal Ultrasound Catheter is a product of Biosense Webster, Inc. (a Johnson & Johnson company) that will hold the 510(k) clearance (K240050) for this device.

SwiftLink Plus Connector connects AcuNav Crystal and SoundStar Crystal Ultrasound Catheters to ACUSON P500 and ACUSON P500 ICE Ultrasound Systems. SwiftLink Plus connector is equivalent to SwiftLink connector previously cleared on the ACUSON P500(K213487) that connects AcuNav 8F/10F and SoundStar eco 8F/10F/eco 10F catheters to ACUSON P500.

- New model introduction
  - This submission includes additional model name, ACUSON P500 ICE. The proposed ACUSON P500 ICE system is substantially equivalent to ACUSON P500(K213487) with regards to intended use, Indications for use, technological characteristics (Transducers, accessories and software features) and safety and effectiveness. All of technological characteristics are migrated (identical SW & HW platform) from the predicate device, ACUSON P500 (K213487), and there is no new feature or transducer compared to the predicate. Only the Panoramic 2D Imaging (SieScape) software feature is not supported or accessible for this model.

7. Nonclinical Data

The ACUSON P500 and P500 ICE 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
- IEC TR 60601-4-2 Edition 1.0 2016-05: Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- 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 the measurement accuracy

8. Clinical Data

Since the ACUSON P500 and P500 ICE 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 systems have accumulated a long history of safe and effective performance. Therefore, it is the opinion of Siemens Medical Solutions USA, Inc. that the ACUSON P500 and P500 ICE systems are substantially equivalent with respect to safety and effectiveness to the predicate device currently cleared for marketing.