Siemens Medical Solutions USA, Inc.
% Sulgue Choi
Regulatory Affairs
22010 S.E. 51st Street
ISSAQUAH WA 98029

February 11, 2022

Re: K213487
Trade/Device Name: ACUSON P500 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: January 18, 2022
Received: January 24, 2022

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 (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,

Jessica Lamb
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213487

Device Name
ACUSON P500 Ultrasound System

Indications for Use *(Describe)*
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.
Note: This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Society of Echocardiography Carotid Intima-Media Thickness Task Force. Endorsed by the Society for Vascular imaging."

Operating Mode
2D-Mode
2D-Mode with Harmonics Imaging
Color flow Doppler
Color (Velocity)
Power (Energy)
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 imaging transducers
Auxiliary Continuous Wave Doppler for pencil transducers
M-Mode
M-Mode with Harmonics Imaging
Anatomical M-Mode
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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K213487

510(k) Summary

Date: February 8, 2022

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

Secondary Contact Person: SeongMin Han
Tel: +82 10 4697 8360
E-mail: seongmin.han@siemens-healthineers.com

2. Device Name: ACUSON P500 Ultrasound System

Common Name: Ultrasound System with Accessories

Classification:

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

Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX
Diagnostic Intravascular Catheter	870.1200	90-OBJ
Biopsy Needle Guide Kit	892.1560	90-OIJ

Manufacturing Site: Siemens Healthineers, Ltd.
2nd ~ 3rd Floor, 143, Sunhwan-ro, Jungwon-gu, Seongnam-si,
Gyeonggi-do, Republic of Korea

3. Legally Marketed Predicate Devices

The ACUSON P500 Ultrasound System is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to the following company's own products.

Predicate device:	ACUSON P500 (K163396)
Reference device(s):	ACUSON Juniper (K201130)
	ACUSON Redwood (K210743)

4. Device Description

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

5. Intended Use/Indications for Use

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.

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Note: This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Society of Echocardiography Carotid Intima-Media Thickness Task Force. Endorsed by the Society for Vascular imaging."

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M-Mode
M-Mode with Harmonics Imaging
Anatomical M-Mode
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. Summary of Technological Characteristics and Determination of Substantial Equivalence

The modified ACUSON P500 Ultrasound System is substantially equivalent to the company's own previously cleared predicate ACUSON P500 (K163396), the ACUSON Juniper (K201130) and the ACUSON Redwood (K210743) with regard to both intended use and technological characteristics. Both the modified ultrasound system under this review and the predicate ultrasound systems function in the same manner as all diagnostic ultrasound systems and transducers.

The submission device differs from the predicated devices as following:

- The modified ACUSON P500 Ultrasound System includes the addition of the 11M3, 18H5, 5VT transducers which were already cleared on the ACUSON Juniper (K201130).
- The modified ACUSON P500 Ultrasound System includes the addition of the Transesophageal and Lung applications which were already cleared on the ACUSON Juniper (K201130).
- The modified ACUSON P500 Ultrasound System includes the addition of VVI(Velocity Vector Image) and AMM(Anatomical M-Mode) software features which were already cleared on the ACUSON Juniper (K201130).
- The modified ACUSON P500 Ultrasound System includes the expansion of TCD(Transcranial Doppler), Lung, FAST(Focused assessment with Sonography in Trauma) clinical applications for P4-2, which were already cleared on the ACUSON Juniper (K201130).
- The modified ACUSON P500 Ultrasound System includes the expansion of Lung, FAST(Focused assessment with Sonography in Trauma) clinical applications for CH5-2, which were already cleared on the ACUSON Juniper (K201130).
- The modified ACUSON P500 Ultrasound System includes the expansion of Lung clinical application for VF10-5, which was already cleared on the ACUSON Juniper (K201130).
- The modified ACUSON P500 Ultrasound System includes the expansion of Lung clinical application for L10-5v, which was already cleared on the ACUSON Juniper (K201130).
- The modified ACUSON P500 Ultrasound System includes the update wording of the Clinical application from 'Neonatal' to 'Neonatal Cephalic' which was already cleared on the ACUSON P500 (K163396).
- The modified ACUSON P500 Ultrasound System includes the addition of eSieLink software feature which was already cleared on the ACUSON Redwood (K210743).
- The modified ACUSON P500 Ultrasound System includes the addition of Hibernation(Quick boot) feature.

All other hardware and software features of the ACUSON P500 Ultrasound device remain unchanged. The foundation of the ACUSON P500 (this submission) is the ACUSON P500(K163396) with features and transducers integrated with the ACUSON P500(K163396) hardware and the ACUSON P500 (this submission) reuse software developed for P500(K163396) mainly as well as 11M3, 18H5, 5VT transducer and VVI(Velocity Vector Image) feature from Juniper (K201130), eSieLink feature from Redwood (K210743).

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

Feature / Characteristic	**ACUSON P500** This Submission	**ACUSON P500 K# 163396** Predicate device	**ACUSON Juniper K# 201130** Reference device	**ACUSON Redwood K# 210743** Reference device
Indications for Use:				
▪ Fetal	√	√		
▪ Abdominal	√	√		
▪ Pediatric	√	√		
▪ Small Organ	√	√		
▪ Cardiac	√	√		
▪ Transrectal	√	√		
▪ Transvaginal	√	√		
▪ Vascular (Peripheral vessel Arterials, Peripheral vessel Venous, Cerebrovascular, Transcranial Doppler)	√	√ (Peripheral vessel Arterials, Peripheral vessel Venous, Cerebrovascular)	√ (Transcranial Doppler)	
▪ Musculo-skeletal (conventional)	√	√		
▪ Musculo-skeletal (superficial)	√	√		
▪ Neonatal cephalic	√	√		

Feature / Characteristic	**ACUSON P500** This Submission	**ACUSON P500** **K# 163396** Predicate device	**ACUSON Juniper** **K# 201130** Reference device	**ACUSON Redwood** **K# 210743** Reference device
▪ Emergency Medicine (Emergency Medicine, Focused Assessment with Sonography for Trauma)	√	√ (Emergency Medicine)	√ (FAST clinical application in Abdominal)	
▪ Intracardiac	√	√		
▪ Trans-esophageal	√		√	
▪ Lung	√		√ (Lung clinical application in Abdominal)	
Frequencies Supported:	√ (1.0MHZ~18MHz)	√ (1.0MHZ~18MHz)	√ (2.0MHz~17MHz)	
Modes:				
▪ B	√	√		
▪ M	√	√		
▪ PWD (Pulsed Wave Doppler)	√	√		
▪ CWD (Continuous Wave Doppler)	√	√		
▪ PW DTI (Doppler Tissue Image)	√	√		
▪ Color Doppler	√	√		
▪ Power Doppler	√	√		
▪ Combined (BMDC)	√	√		
Features:				

Feature / Characteristic	**ACUSON P500** This Submission	**ACUSON P500 K# 163396** Predicate device	**ACUSON Juniper K# 201130** Reference device	**ACUSON Redwood K# 210743** Reference device
▪ THI (Tissue Harmonic Imaging)	√	√		
▪ M-THI	√	√		
▪ Panoramic 2D Imaging (SieScape)	√	√		
▪ Dual-Beam Processing	√	√		
▪ Quad-Beam Processing	√	√		
▪ Clip Capture	√	√		
▪ Spectral DTI	√	√		
▪ Stress Echo	√	√		
▪ 2D(color) DTI	√	√		
▪ DIMAQ (PIMS Workplace)	√	√		
▪ Vascular Enhancement (Clarify VE)	√	√		
▪ eSieImage	√	√		
▪ Advance SieClear	√	√		
▪ Multiple Frequency Imaging(MultiHertz)	√	√		
▪ Digital Architecture	√	√		
▪ DICOM SR Vascular	√	√		
▪ DICOM SR OB/GYN	√	√		
▪ DICOM SR Cardiac	√	√		

Feature / Characteristic	**ACUSON P500** This Submission	**ACUSON P500 K# 163396** Predicate device	**ACUSON Juniper K# 201130** Reference device	**ACUSON Redwood K# 210743** Reference device
▪ Dynamic TCE	√	√		
▪ Syngo AHP	√	√		
▪ eSieMeasure	√	√		
▪ eSieScan	√	√		
▪ Enhanced Needle Visualization	√	√		
▪ Probe Saver	√	√		
▪ Intracardiac Echocardiography (ICE) Imaging	√	√		
▪ CARTOSOUND Communication	√	√		
▪ Velocity Vector Image (VVI)	√		√	
▪ Anatomical M-mode (AMM)	√		√	
▪ eSieLink	√			√
▪ Hibernation(Quick boot)	√			
Wireless	√	√		
Monitor: 15.4”WXGA(FPD)	√	√		
Output Display Standard (Track 3)	√	√		
Patient Contact Materials	Tested to ISO 10993-1	Tested to ISO 10993-1		
UL 60601-1 Certified	√	√		

Feature / Characteristic	**ACUSON P500** This Submission	**ACUSON P500 K# 163396** Predicate device	**ACUSON Juniper K# 201130** Reference device	**ACUSON Redwood K# 210743** Reference device
Indications for Use	√	√		

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

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 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)
- Safety and EMC Requirements for Medical Equipment
  - 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, Medical electrical 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 2018-08-01, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process / Corrected and reprinted in 2018-10

8. A summary discussion of the clinical tests submitted, referenced, or relied on for a determination of substantial equivalence.

Since the ACUSON P500 Ultrasound System uses the same technology and principles as existing devices, clinical studies were not required to support substantial equivalence.

9. Summary

The ACUSON P500 Ultrasound System is verified and validated according to the company's design control process.

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 P500 system is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.