DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Siemens Medical Solutions USA, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street, NW
BUFFALO MN 55313

February 9, 2015

Re: K150050
Trade/Device Name: Acuson P500 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: January 5, 2015
Received: January 12, 2015

Dear Mr. Job:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150050

Device Name
Acuson P500 Ultrasound System

Indications for Use *(Describe)*
The ACUSON P500 ultrasound system is intended for diagnostic ultrasound imaging and fluid flow analysis for the following applications: Fetal, Abdominal, Small Parts, OB/GYN, Pelvic, Cardiovascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures fetal, abdominal, small organ, transrectal, transvaginal, cardiovascular, peripheral vessel, musculoskeletal (conventional), and musculoskeletal (superficial) 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.

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.

510(k) Summary
Prepared December 15, 2014

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

Manufacturing Facility
SIEMENS LTD SEOUL
2nd -3rd floor, 143, Sunhwan-ro,
Jungwon-gu, Seongnam-si, Gyeonggi-do,
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Contact Person: Shelly Pearce
Telephone: (650) 279-0134
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Device Name: ACUSON P500 Ultrasound System

Common Name: Diagnostic Ultrasound System with Accessories

Classification:

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

Ultrasonic Pulsed Doppler Imaging System	FR # 892.1550	Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System	FR # 892.1560	Product Code 90-IYO
Diagnostic Ultrasound Transducer	FR # 892.1570	Product Code 90-ITX

A. 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 our current product, the ACUSON X300 ultrasound system (K121699) and ACUSON S2000 ultrasound system (K140959).

B. Device Description:

The ACUSON P500 is a multi-purpose mobile, software controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to acquire harmonic 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, Tissue Doppler Image, Power (Amplitude) Doppler Mode and a combination of modes on a Flat Panel Display.

C. Intended Use

The ACUSON P500 ultrasound imaging system is intended for the following applications: Fetal, Abdominal, Small Parts, OB/GYN, Pelvic, Cardiovascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures fetal, abdominal, small organ, transrectal, transvaginal, cardiovascular, peripheral vessel, musculoskeletal (conventional), and musculoskeletal (superficial) 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.

D. Substantial Equivalence

The ACUSON P500 is substantially equivalent to the ACUSON X300, cleared via K121699, and ACUSON S2000. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

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

Feature / Characteristic	Predicate Device ACUSON X300 (K121699)	Predicate Device ACUSON S2000 (K140959)	Submission Device ACUSON P500
Indications for Use:			
▪ Fetal	√	√	√
▪ Abdominal	√	√	√
▪ Small Organ	√	√	√
▪ Cardiac	√	√	√
▪ Transrectal	√	√	√
▪ Transvaginal	√	√	√
▪ Peripheral vessel	√	√	√
▪ Musculo-skeletal (conventional)	√	√	√
▪ Musculo-skeletal (superficial)	√	√	√
▪ Emergency Medicine	√	√	√
Center Frequencies Supported:			
▪ 2.0 MHz	√	√	√
▪ 2.5 MHz	√	√	√
▪ 3.0 MHz	√	√	√
▪ 3.5 MHz	√	√	√
▪ 4.0 MHz	√	√	√
▪ 5.0 MHz	√	√	√
▪ 5.5 MHz	√	√	√
▪ 6.0 MHz	√	√	√
▪ 6.5 MHz	√	√	√
▪ 7.5 MHz	√	√	√
▪ 8.0 MHz	√	√	√
▪ 9.0 MHz	√	√	√
▪ 10.0 MHz	√	√	√

Feature / Characteristic	Predicate Device ACUSON X300 (K121699)	Predicate Device ACUSON S2000 (K140959)	Submission Device ACUSON P500
▪ 11.0 MHz	√	√	√
Modes:			
▪ B	√	√	√
▪ M	√	√	√
▪ PWD (Pulsed Wave Doppler)	√	√	√
▪ SCW (Steerable CW)	√	√	√
▪ D (Color Doppler)	√	√	√
▪ Power Doppler (Amplitude Doppler)	√	√	√
▪ Combined (BM, BC, BCM, BCD)	√	√	√
▪ THI (Tissue Harmonic Imaging)	√	√	√
▪ M-THI	√	√	√
Features:			
▪ 3D Imaging (3-Scape)	√	√	--
▪ 3D Measurements	√	√	--
▪ 4D Basic Imaging (fourSight 4D)	√	√	--
▪ Panoramic 2D Imaging (SieScape)	√	√	--
▪ Cardiac Imaging physiological signal display multiplane TEE fourSight TEE Imaging	√	√	--
▪ Dual-Beam Processing	√	√	√
▪ Quad-Beam Processing	√	√	√
▪ SynAps	√	√	--
▪ Clip Capture	√	√	√
▪ Tissue Grayscale Optimization (TGO)	√	√	--
▪ Spectral DTI	√	√	--
▪ Axius OB Automated Calipers	√	√	--
▪ Steerable CW	√	√	√
▪ Stress Echo	√	√	--
▪ 2D(color) DTI	√	√	--
▪ Image Arena reporting S/W	√	√	--
▪ DIMAQ (PIMS Workplace)	√	√	√
▪ Vascular Enhancement (Clarify VE)	√	√	--
▪ eSieImage	--	√	√
▪ Advance SieClear	--	√	√
▪ Multiple Frequency Imaging(MultiHertz)	√	√	√
▪ Digital Architecture	√	√	√
▪ Fully integrated DICOM	√	√	√
▪ Dynamic TCE	√	√	√
▪ AHP	√	√	--
▪ Monitor: 15.4"WXGA (FPD)	√ (17" FPD)	√ (19" FPD)	√
▪ Wireless	√	√	√

Feature / Characteristic	Predicate Device ACUSON X300 (K121699)	Predicate Device ACUSON S2000 (K140959)	Submission Device ACUSON P500
# Channels	128	192	64
Output Display Standard (Track 3)	√	√	√
Patient Contact Materials	Tested to ISO 10993-1	Tested to ISO 10993-1	Tested to ISO 10993-1
UL60601-1 Certified	√	√	√

E. 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 has been found to conform with applicable medical device safety standards. The system complies with the following voluntary standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
  - EN/IEC 60601-1
  - EN/IEC 60601-1-1
  - EN/IEC 60601-1-2
  - EN/IEC 60601-1-6
  - EN/IEC 62304
  - EN/IEC 62366
  - EN/IEC 60601-2-18
  - EN/IEC 60601-2-25
- ISO 10993-1 Biocompatibility

Cleared patient contact materials, electrical and mechanical safety are unchanged.

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

Since the P500 uses the same technology and principles as existing devices, clinical data is not required.

G. 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 with 21 CFR 820 Quality System Regulation and ISO 13485:2003 quality system standards. The product is designed to conform with applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore it is the opinion of Siemens Medical that the P500 is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

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