DEC 2 4 2013

510(k) Summary
Prepared April 17, 2013

1. Sponsor:

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

Contact Person:

Shelly Pearce
Telephone: (650) 694-5988
Fax: (650) 694-5580

2. Device Name: Acuson S2000 and S3000 Diagnostic Ultrasound Systems

Common Name: Diagnostic Ultrasound System

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
Diagnostic Ultrasound Catheter	FR # 870.1200	Product Code OBJ

3. Legally Marketed Predicate Devices

The Acuson S2000 and S3000 Ultrasound Systems are substantially equivalent to the company's own S2000 and S3000 Ultrasound Systems and Supersonic Imagine Shearwave Elastography (K111674, K122825, K112255, K121329)

4. Device Description:

The S2000 and S3000 Ultrasound Systems are multi-purpose mobile, software controlled diagnostic ultrasound systems with an on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of modes, or Harmonic Imaging and 3D/4D Imaging on a Flat Panel Display. It is substantially equivalent to the S2000 (K111674) and S3000 system (K122825) which are legally marketed devices.

5. Intended Use

The S2000 and S3000 ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures {fetal, abdominal, intraoperative, intraoperative neurological, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, trans-esophageal, transrectal, transvaginal, peripheral vessel, musculo-skeletal (conventional), musculo-skeletal (superficial) and neonatal cardiac} and calculation packages that provide information 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. 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 Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

The Acuson Acunav Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.

6. Summary of Technological Characteristics – New Device Compared to Predicate

Feature / Characteristic	Submission Device S2000	Submission Device S3000	Acuson S3000 K122825	Acuson S2000 K111674	Supersonic Imagine K112255 / K121329
Indications for Use:					
▪ Fetal	√	√	√	√	
▪ Abdominal	√	√	√	√	√
▪ Intraoperative abdominal and vascular	√	√	√	√	
▪ Intraoperative neurological	--	--	--	--	--
▪ Pediatric	√	√	√	√	√
▪ Small Organ	√	√	√	√	√
▪ Neonatal cephalic	√	√	√	√	
▪ Adult Cephalic	√	√	√	√	
▪ Cardiac	√	√	√	√	
▪ Trans-esophageal	√	√	√	√	
▪ Transrectal	√	√	√	√	√
▪ Transvaginal	√	√	√	√	√
▪ Peripheral vessel	√	√	√	√	√
▪ Laparoscopic	--	--	--	--	--
▪ Musculo-skeletal (conventional)	√	√	√	√	√
▪ Musculo-skeletal (superficial)	√	√	√	√	√
Center Frequencies Supported:					
▪ 2.0 MHz	√	√	√	√	√
▪ 3.0 MHz	√	√	√	√	√
▪ 3.2 MHz	√	√	√	√	√

Feature / Characteristic	Submission Device S2000	Submission Device S3000	Acuson S3000 K122825	Acuson S2000 K111674	Supersonic Imagine K112255 / K121329
▪ 3.3 MHz	√	√	√	√	√
▪ 4.2 MHz	√	√	√	√	√
▪ 4.4 MHz	√	√	√	√	√
▪ 4.8 MHz	√	√	√	√	√
▪ 5.0 MHz	√	√	√	√	√
▪ 5.2 MHz	√	√	√	√	√
▪ 6.0 MHz	√	√	√	√	√
▪ 6.5 MHz	√	√	√	√	√
▪ 6.9 MHz	√	√	√	√	√
▪ 9.5 MHz	√	√	√	√	√
▪ 10.0 MHz	√	√	√	√	√
Modes:					
▪ B	√	√	√	√	√
▪ Parallel processing in B mode	√	√	√	√	√
▪ M	√	√	√	√	
▪ PWD (Pulsed Wave Doppler)	√	√	√	√	√
▪ CWD (Continuous Wave Doppler)	√	√	√	√	√
▪ D (Color Doppler)	√	√	√	√	√
▪ Amplitude Doppler	√	√	√	√	√
▪ Combined (BMDC)	√	√	√	√	√
Features:					
Quad processing in color	√	√	√	√	
▪ Native™ tissue harmonic imaging	√	√	√	√	
▪ SieScape™ panoramic imaging	√	√	√	√	
▪ Color SieScape™ panoramic imaging	√	√	√	√	
▪ 3-Scape™ real-time 3D imaging	√	√	√	√	
▪ fourSight™ 4D transducer technology	√	√	√	√	
▪ TEQ™ ultrasound technology	√	√	√	√	
▪ Extend imaging technology	√	√	√	√	
▪ Cardiac Imaging physiological signal display	√	√	√	√	
▪ syngo ® Auto OB measurements	√	√	√	√	
▪ Advanced SieClear™ spatial compounding	√	√	√	√	
▪ STIC (Fetal Heart Imaging)	√	√	√	√	
▪ Amnioscopic rendering	√	√	√	√	
▪ Cadence contrast agent imaging	√	√	√	√	
▪ Clarify™ vascular enhancement technology	√	√	√	√	
▪ eSie™ Touch elasticity imaging	√	√	√	√	√
▪ syngo ® Auto Left heart	√	√	√	√	
▪ syngo ® Velocity Vector Imaging	√	√	√	√	
▪ Semi Auto-segmentation (eSie Calc)	√	√	√	√	

Feature / Characteristic	Submission Device S2000	Submission Device S3000	Acuson S3000 K122825	Acuson S2000 K111674	Supersonic Imagine K112255 / K121329
▪ Custom Tissue Imaging / Speed of Sound	√	√	√	√	
▪ AHP	√	√	√	√	
▪ VTQ	√	√			√
▪ 18L6HD Transducer	√	√	√	√	
▪ 6C1HD Transducer	√	√	√	√	
▪ 8C3HD Transducer		√	√		
▪ Monitor: FPD	√	√	√	√	√
Output Display Standard (Track 3)	√	√	√	√	√
Patient Contact Materials	Tested to ISO 10993-1	Tested to ISO 10993-1	Tested to ISO 10993-1	Tested to ISO 10993-1	Tested to ISO 10993-1
UL 60601-1 Certified	√	√	√	√	√

Shear Wave Elasticity Imaging Software	VTQ	Supersonic Imagine Aixplorer	Comments
Comparable Exam Types	Abdomen, Breast, Thyroid	Abdomen, Breast, Thyroid	
Transducer for same Exam Types	6C1 HD, 4C1, 4V1, 9L4	SC6-1 SL15-4	
Operating Mode	Single Frame	Low Frame Rate Real Time	Note 1
Cool Down period before live imaging resumes	Yes (variable, ~1-3 sec)	No	Note 1
Push Pulse sequence	Dual Push Beams; one on each side of measurement ROI	Low (variable with FOV size) Reference Figure 13 in Supersonic White Paper	Note 1
Multiple Push Pulse Focal Zones	No (Single focal position tracks with ROI location in depth)	"Mach Cone"	In both cases, radiation force uniformity is maintained with depth by optimizing push beam focus at region of interest. "Mach Cone" is the Supersonic term for compound transmit focusing
Two Dimensional Display with Elasticity Region of Interest	No	Yes	"Supersonic Imagine has implemented a two dimensional image display representing shear wave speed or Young's modulus. The region of interest size is adjustable within limits. A potential advantage is the ability to visualize variability of the elasticity parameter over a wider area of interest, however this is visual reference without quantification of variance. Outside the USA, the ability to get a mean value is provided for the larger area or with reduced measurement ROI size, a localized value. This feature is not cleared in the USA. VTQ provides a mean shear wave

			speed over a predefined region of interest that is not adjustable. For the 4C1, 6C1 HD and 4V1 abdomen transducers, the ROI size is 10mm x 5mm. For the 9L4 transducer, the ROI size is 5 x 5 mm. Multiple measurements can be made over larger areas and statistics for Mean, Median, Standard Deviation and IQR (Interquartile range) are provided for analyzing multiple measurements. There is no evidence to suggest one method is more accurate than the other, therefore we believe they are equivalent in clinical use."
Localized Quantitative Shear Wave Velocity measurement	Yes	Yes - Predicate not cleared in the U.S.A.	
Localized Quantitative Young's Modulus measurement	No	Yes - Predicate not cleared in the U.S.A.	Supersonic Imagine has implemented the shear wave velocity scale in the color bar which indicates relative shear wave speed in the image and has been cleared in the U.S. Young's modulus is not cleared. Siemens VTQ is equivalent to Supersonic except Siemens is requesting clearance for point measurements in addition to displaying shear wave velocity on the color bar. When Young's modulus is displayed (kPa), assumptions are made regarding tissue density and viscosity that may not be correct in a wide range of biological tissues and is therefore an indirect measurement. Shear wave velocity is a direct measurement.
Localized Shear Wave Velocity measurement area	6C1 HD, 4C1, 4V1: 10mm (height) by 6 mm (width) 9L4: 5mm (height) by 6 mm (width)	Yes - Predicate not cleared in the U.S.A.	With VTQ, shear wave velocity estimates must pass a confidence interval check (≥0.8) to display a value, otherwise an "x.xx" result is displayed.
Shear Wave Propagation "Movie" (clip)	No	Yes	The Supersonic shear wave propagation movie provides information specific to their implementation of shear wave imaging, as noted in Note 1.
Shear Wave Velocity Measurement Range	0.5-5.5 m/sec (6C1 HD, 4C1, 4V1) 0.5-8.4 m/sec (9L4)	SC6-1: 0-10 m/sec (default 0-3.2 m/sec) SL15-4: 0-10 m/sec	Siemens has chosen a lower velocity cutoff of 0.5 m/s to avoid potential erroneous shear wave velocity estimates. In in-vivo studies, shear wave velocities below 0.5 m/s have not been encountered so there is no impact on clinical efficacy. For abdomen (liver) applications, in several in-vivo studies the maximum recorded values did not exceed 4.4 m/sec.
Color Coded Shear Wave Velocity Display	No	Yes	
Adjustable Maximum and Minimum Velocity Scale	No	Yes	
In Color Code, Red is 'stiff' and blue is 'soft'	N/A	Yes	
Color map is transparent over B mode display	N/A	Yes	
Other system features:			

B Mode Imaging	Yes	Yes	
Pulse Wave Doppler Imaging	Yes	Yes	
Color Flow Doppler Imaging	Yes	Yes	
Spatial Compound Imaging	Yes	Yes	
Speckle Reduction Image Processing	Yes	Yes	
Tissue Harmonic Imaging	Yes	Yes	

Note 1:

There are differences in push pulse sequencing and shear wave detection between the predicate device (Supersonc Aixplorer) and Siemens VTQ. Siemens uses focused push beams on each side of the measurement ROI and a fixed number of closely spaced focused detection beams resulting in higher signal to noise ratio in shear wave imaging than the predicate device. A reduced push beam mechanical index is used on the Aixplorer as compared to the constant value of 1.7 with VTQ, which allows pseudo-real time operation on the Aixplorer of approximately 1 frame per second. The user is required to compound the image at the region of interest over several seconds with the Aixplorer to allow the image to "build up" over several frames to improve signal to noise ratio. VTQ is a single frame image acquisition that allows higher signal to noise ratio without image compounding and generates a more consistent shear wave velocity estimation based on our experience in in-vivo studies.

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

The devices have 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
- IEC 1157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

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

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

The S2000, S3000 and Aixplorer use the same technology and principles as existing devices, clinical data is not required.

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 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 devices are substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

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

December 24, 2013

Siemens Medical Solutions USA, Inc.
c/o Ms. Shelly Pearce
Regulatory Affairs
1230 Shorebird Way
MOUNTAIN VIEW CA 94043

Re: K131164
Trade/Device Name: Acuson S2000 and S3000 Diagnostic Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX, OBJ
Dated: November 19, 2013
Received: November 22, 2013

Dear Ms. Pearce:

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.

This determination of substantial equivalence applies to the following transducers intended for use with the Acuson S2000 and S3000 Diagnostic Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

CW2	CW5	EC9-4 Curved Array
9L4 Linear Array	14L5 Multi-D Array	4P1 Phased Array
6C2 Curved Array	4C1 Curved Array	6C1HD Curved Array
4V1 Phased Array	10V4 Phased Array	14L5 SP Linear Array
7CF2 Curved Array	9EVF4 Curved Array	V5Ms Multiplane TEE
8V3 Phased Array	4V1c Phased Array	6L3
EV8C4	8C3HD Curved Array	18L6 HD Linear Array
V7M TEE	ACUNAV 8F	ACUNAV 10F

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

1.3 Indications for Use

A. 510(k) Number (if known): K131164

Device Name: S2000 and S3000 Diagnostic Ultrasound Systems

Indications for Use:
The S2000 and S3000 ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures (fetal, abdominal, intraoperative, intraoperative neurological, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, trans-esophageal, transrectal, transvaginal, peripheral vessel, musculo-skeletal (conventional), musculo-skeletal (superficial) and neonatal cardiac) and calculation packages that provide information 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 Acuson Acunav Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.

Prescription Use ____X___ (Part 21CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health (OIR)

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