K072676

SECTION 11

510(k) Summary

DEC 18 2007

Sponsor: Siemens Medical Solutions USA, Inc.,
Ultrasound Division
1230 Shorebird Way
Mountain View, California 94043

Contact Person: Martina Vogt
Telephone: (425) 557 1434
Fax: (425) 391 9198

Submission Date: September 19, 2007

Device Name: ACUSON X300™ Diagnostic Ultrasound System
SONOVISTA X300 Diagnostic 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
Diagnostic Intravascular Catheter	FR # 870.1200	Product Code 74-DQO

A. Legally Marketed Predicate Devices
The Siemens Acuson X300 ultrasound system is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to our current product, the Siemens Acuson X300 ultrasound system (K071036, K061946).

B. Device Description:

The Siemens Acuson X300 has been designed to meet the following product safety 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 61157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

C. Intended Use

The Siemens Acuson X300 ultrasound imaging system is intended for the following applications: General Radiology, Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Neonatal/Adult Cephalic, Cardiac, Transesophageal, Pelvic, Transcranial, OB/GYN, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

D. Substantial Equivalence

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

E. Performance Data

The Acuson X300 modifications are verified and validated according to the company's design control process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2007

Ms. Martina Vogt
Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
1230 Shorebird Way
MOUNTAIN VIEW CA 94043

Re: K072676
Trade/Device Name: ACUSON X300 Diagnostic Ultrasound Systems
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX, and DQO
Dated: November 14, 2007
Received: November 15, 2007

Dear Ms. Vogt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the ACUSON X300 Diagnostic Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

P5-1 Phased Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

SECTION 7

Intended Use of the Device

Intended Use:

The Siemens Acuson X300 ultrasound imaging system is intended for the following applications: General Radiology, Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Neonatal/Adult Cephalic, Cardiac, Transesophageal, Pelvic, Transcranial, OB/GYN, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072676

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **ACUSON X300 Diagnostic Ultrasound Systems**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
Intraoperative (Note 6)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
Intraoperative Neurological		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
Small Organ (Note 1)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
Cardiac		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
Transesophageal		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9
Transrectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
Transurethral										
Intravascular		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
Laparoscopic										
Musculo-skeletal Conventional		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
Musculo-skeletal Superficial		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
Other (specify)		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10

N = new indication; P = previously cleared by K071036; E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging
Note 8 SieClear multi-view spatial compounding
Note 9 Tissue Equalization Technology
Note 10 Intracardiac imaging

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072676

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **P5-1** Phased Array Transducer for use with :
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,9
Abdominal		N	N	N	N	N	N		BMDC	Note 2,3,5,6,7,8,9
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,9
Small Organ (Note 1)										
Neonatal Cephalic		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,9
Adult Cephalic		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,9
Cardiac		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,9
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		N	N	N	N	N	N		BMDC	Note 2,3,4,5,7,8,9
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
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Prescription Use (Per 21 CFR 801.109)