510(K) SUMMARY

JAN - 4 2007

ACUSON P10™ Diagnostic Ultrasound System

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

1. **Submitted By:**

Siemens Medical Solutions USA, Inc., Ultrasound Division
1230 Shorebird way
Mountain View, CA 94043

Contact Person:
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Regulatory Affairs Specialist
Phone: (650) 694 5653
FAX: (650) 943 7053

Date Prepared:
11/15/2006

2. **Proprietary Name:**
ACUSON P10™ Ultrasound System

Common/ Usual Name:
Diagnostic Ultrasound System with Accessories

Classification Name:

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

3. **Predicate Device:**

- K052331, 11/9/2005, ACUSON Cypress™ Diagnostic Ultrasound System
- K052410, 9/22/2005, ACUSON Sequoia™ Diagnostic Ultrasound System
- K020353, 2/13/2002, SONOLINE G50 & G60 S Diagnostic Ultrasound System
- K994096, 12/20/1999, Sonosite SonoHeart™ Hand-Carried Echocardiography System

4. **Device Description:**
The ACUSON P10™ is a general purpose, hand-held, software-controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bioeffect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in B-Mode, Color Doppler Mode, a combination of these modes, and Harmonic Imaging, on an LCD display.

The ACUSON P10 has been designed to meet the following product safety standards:

- UL 60601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety
- CSA C22.2 No. 60601-1, Safety Requirements for Medical Equipment
- NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
- EN 60601-1
- EN 60601-1-1
- EN 60601-1-2
- EN 60601-1-2-37
- EN 60601-1-4
- IEC 61157 Declaration of Acoustic Power
- ISO 10993 Biocompatibility
- The system's acoustic output is in accordance with ALARA principle (as low as reasonably achievable)

5. **Intended Uses:**
The P10 ultrasound imaging system is intended for the following applications: General Radiology, Abdominal, OB/GYN, Fetal, Pediatric, Adult Cephalic, and Cardiac applications.

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

6. **Technological Comparison to Predicate Device:**
The ACUSON P10™ is substantially equivalent to the predicate devices listed in paragraph 3 above. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures to aid in diagnosis.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 4 2007

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

Re: K063761
Trade Name: ACUSON P10 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYO, IYN, and ITX
Dated: December 16, 2006
Received: December 20, 2006

Dear Mr. Job:

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 P10 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

P4-2 (2-4 MHz 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 Andrew Kang at (240) 276-3666.

Sincerely yours,

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

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063761

Device Name: **ACUSON P10™ Diagnostic Ultrasound System**

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)	Tissue Harmonic Imaging
Ophthalmic										
Fetal		N				N			BC	N
Abdominal		N				N			BC	N
Intraoperative										
Intraoperative Neurological										
Pediatric		N				N			BC	N
Small Organ										
Neonatal Cephalic										
Adult Cephalic		N				N			BC	N
Cardiac		N				N			BC	N
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication

(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)

David G. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063761

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K063761

Device Name: **P4-2** (2-4MHz Phased Array) Transducer for use with:
ACUSON P10™ Diagnostic Ultrasound System

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)	Tissue Harmonic Imaging
Ophthalmic										
Fetal		N				N			BC	N
Abdominal		N				N			BC	N
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		N				N			BC	N
Small Organ										
Neonatal Cephalic										
Adult Cephalic		N				N			BC	N
Cardiac		N				N			BC	N
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)										

N = new indication

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Segstrom

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063761