K060879

SECTION 11

510(k) Summary of Safety and Effectiveness

APR 19 2006

Sponsor: Siemens Medical Solutions USA, Inc.,
Ultrasound Division
1230 Shorebird Way
P.O. Box 7393
Mountain View, California 94039-7393

Contact Person: Patrick Lynch
Sr. Regulatory Affairs Specialist
Telephone: (425) 557-1825
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Submission Date: March 22, 2006

Device Name: EC9-4 Ultrasound Transducer

Common Name: Diagnostic Ultrasound Transducer

Classification:

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

21 CFR 892.1550

	FR #	Product Code
Diagnostic Ultrasound Transducer	892.1570	90-ITX

Predicate Devices:

The EC9-4 transducer has already been cleared on the following Siemens Medical Solutions' ultrasound platform:

- ACUSON Antares™ ultrasound platform (#K050034)

Device Description:

Presently cleared **EC9-4** endocavity curved array ultrasound transducer is primarily indicated for transrectal and transvaginal, fetal and neonatal and small parts applications on the ACUSON Antares ultrasound imaging platform.

Intended Use:

EC9-4 is a convex array ultrasound transducer intended for fetal, small organ, neonatal cephalic, transvaginal and transrectal applications on the ACUSON Antares™ ultrasound system.

1. **ACUSON Antares™ ultrasound system** is intended for use in the following applications:

   General Radiology, Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN, Cardiac, Transesophageal, Pelvic, Neonatal/Adult Cephalic, 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.

The **Antares ultrasound system** has been designed to conform to the following *product safety standards*:

- UL 60601-1, Safety Requirements for Medical Equipment
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-2, 1998, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- AIUM/NEMA UD-3, 1998, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- 93/42/EEC Medical Device Directive
- Safety and EMC Requirements for Medical Equipment
- EN 60601-1
  - EN 60601-1-1
  - EN 60601-1-2
  - EN 60601-2-37
- ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

The systems' acoustic output is in accordance with ALARA principle (as low as reasonably achievable)

Technological Comparison to Predicate Devices:

EC9-4 ultrasound transducer is substantially equivalent in its technology and functionality to the EC9-4 transducer which is already cleared under the following 510(k) premarket notification number: K050034 (ACUSON Antares ultrasound system).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 19 2006

Mr. Patrick Lynch
Senior Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
Ultrasound Division Headquarters
1230 Shorebird Way
P.O. Box 7393
MOUNTAIN VIEW CA 94039-7393

Re: K060879
Trade Name: EC9-4 Ultrasound Transducer
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: March 30, 2006
Received: March 31, 2006

Dear Mr. Lynch:

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 Antares™ Ultrasound System, as described in your premarket notification:

Transducer Model Number
EC9-4

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 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 (301) 443-6597 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, M.D. at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

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

510(k) Number (if known): K060879

Device Name: EC9-4 ultrasound transducer

Indications for Use:

The **EC9-4** endocavity curved array ultrasound transducer is primarily indicated for transrectal and transvaginal, fetal and neonatal and small parts applications on the ACUSON Antares ultrasound imaging platform.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Steven C. Dryden

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060879