K083114
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**510(k) Summary**
**Prepared October 13, 2008**


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


MAR 31 2009


**Contact Person:** Sheila W. Pickering Ph.D.
Telephone: (650) 943 7187
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**Submission Date:** October 13, 2008

**Device Name:** Siemens Acuson P50 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 P50 Ultrasound system is substantially equivalent to the P50 ultrasound system (K072266).

**B. Device Description:**

The Siemens Acuson P50 system 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, 1998 Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, 1998 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

**C. Intended Use**

The Acuson P50 Ultrasound System is intended for diagnostic ultrasound imaging or fluid flow analysis of the human body. The system includes the AcuNav 10F and 8F transducers which are intended for intra-cardiac and intra-luminal visualization of the cardiac and great vessel anatomy and physiology as well as the visualization of other devices in the heart of adult and pediatric patients. The system also includes the SieClear application. SieClear improves contrast resolution when using linear-type transducers by interrogating the target tissue from different imaging angles and adding these images together to create a composite image. This is performed in real-time.

## D. Substantial Equivalence

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

## E. Performance Data

The P50 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

Sheila W. Pickering, Ph.D.
Senior Director of Regulatory Affairs
Siemens Medical Solutions USA, Inc.
1230 Shorebird Way, P.O. Box 7393
MOUNTAIN VIEW CA 94039

MAR 31 2009

Re: K083114
Trade/Device Name: ACUSON P50 Diagnostic Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: March 4, 2009
Received: March 6, 2009

Dear Dr. Pickering:

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 P50 Diagnostic Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

AcuNav 10F Intracardiac
AcuNav 8F Intracardiac

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 (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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

# Indications for Use

510(k) Number (if known): K083114

Device Name: ACUSON P50 Ultrasound System

Indications For Use:

The Acuson P50 Ultrasound System is intended for diagnostic ultrasound imaging or fluid flow analysis of the human body. The system includes the AcuNav 10F and 8F transducers which are intended for intra-cardiac and intra-luminal visualization of the cardiac and great vessel anatomy and physiology as well as the visualization of other devices in the heart of adult and pediatric patients. The system also includes the SieClear application. SieClear improves contrast resolution when using linear-type transducers by interrogating the target tissue from different imaging angles and adding these images together to create a composite image. This is performed in real-time.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K083114

K083114



DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ACUSON P50 Ultrasound System
Transducer: (see comments)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|---|
| General (Track I Only) | Specific (Tracks I & III) | B | M | PWD | CWD | Color Dopp[a] | Comb. Modes[b] | Other[c] |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal | P[d] | P | P | | P[d] | P | P[d] |
| | Abdominal | P[d] | P | P | | P[d] | P | P[d] |
| | Intra-operative (Spec.)[e] | P[d] | P | P | | P[d] | P | P[d] |
| | Intra-operative (Neuro) | P | P | P | | P | P | P |
| | Laparoscopic | | | | | | | |
| | Pediatric | P[d] | P | P | | P[d] | P | P[d] |
| | Small Organ (Thyroid, Breast, Testes, etc.) | P[d] | P | P | | P[d] | P | P[d] |
| | Neonatal Cephalic | P | P | P | P | P | P | P |
| | Adult Cephalic | P | P | P | P | P | P | P |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | |
| | Musculo-skel. (Convent.) | P[d] | P | P | | P[d] | P | P[d] |
| | Musculo-skel. (Superfic) | P[d] | P | P | | P[d] | P | P[d] |
| | Intra-luminall | P | P | P | P | P[d] | P | P |
| | Other (Specify) | | | | | | | |
| Cardiac | Cardiac Adult | P | P | P[f] | P | P[g] | P | P |
| | Cardiac Pediatric | P | P | P[f] | P | P[g] | P | P |
| | Trans-esoph. (Cardiac) | P | P | P[f] | P | P[g] | P | P |
| | Other (Specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | P[d] | P | P | | P | P | P[d] |
| | Other (Specify) | | | | | | | |

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD) and (non-directional) Power Doppler.
[b] B+M; B+PWD; B+CWD; B+CD; B+PD.
[c] Harmonic Imaging (HI)
[d] Includes ultrasound guidance for placement of needles & catheters.
[e] Abdominal organs and peripheral vessel.
[f] PW includes PW Doppler Tissue Imaging (DTI).
[g] includes Doppler Tissue Imaging (DTI) .
Includes uses in military field settings in addition to hospital/clinic settings.
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

**Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation**
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K083114

K083114



## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K083114

Device Name: **AcuNav 10F** Intracardiac Transducer for use with : **ACUSON P50 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 | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative (Note 6) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | P | P | P | | BMDC | Note 2,3,7,8,9,10 |
| Small Organ (Note 1) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | P | P | P | P | P | P | | BMDC | Note 2,3,7,8,9, 10 |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | P | P | P | P | P | P | | BMDC | Note 2,3,7,8,9,10 |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (Intra-cardiac) | | P | P | P | P | P | P | | BMDC | Note 2,3,7,8,9,10 |

N = new indication; P = previously cleared by Kxxxxxx; 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

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K083114

K083114



## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K083114

Device Name: **AcuNav 8F** Intracardiac Transducer for use with : **ACUSON P50 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 | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative (Note 6) | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | P | P | P | | BMDC | Note 2,3,7,8,9,10 |
| Small Organ (Note 1) | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | P | P | P | P | P | P | | BMDC | Note 2,3,7,8,9,10 |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | P | P | P | P | P | P | | BMDC | Note 2,3,7,8,9,10 |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (Intra-cardiac) | | P | P | P | P | P | P | | BMDC | Note 2,3,7,8,9,10 |

N = new indication; P = previously cleared by Kxxxxxx; 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

Prescription Use ✓
(Per 21 CFR 801.109)

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510(k) Number K083114