

JUN 30 2011

Siemens Medical Solutions, Inc.
Ultrasound Division

S2000 Ultrasound System
510(k) Submission

510(k) Summary
Prepared May 12, 2011

- 1. Sponsor:** Siemens Medical Solutions, Inc.,
Ultrasound Division
1230 Shorebird Way
Mountain View, California 94043
- Contact Person:** Shelly Pearce
Telephone: (650) 694-5988
Fax: (650) 694-5580
- Submission Date:** May 12, 2011
- 2. Device Name:** Acuson S2000™ Diagnostic Ultrasound System
- 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 modified Acuson S2000™ Ultrasound System is substantially equivalent to the the company's own Acuson Antares and S2000 Ultrasound Systems.

4. Device Description:

The S2000™ Ultrasound System is a multi-purpose mobile, software controlled diagnostic ultrasound system with and 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 our current S2000 product (K093812, K090334, K072786, K081148), and Siemens V7M (K063085), AcuNav 8F and AcuNav 10F (K071234) transducers. These predicates are legally marketed devices.

5. Intended Use

The S2000™ 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 | Acuson S2000 | Acuson Antares K# 063803 |
|---|--------------|--------------------------|
| 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 | √ | √ |
| ▪ 3.3 MHz | √ | √ |

| Feature / Characteristic | Acuson S2000 | Acuson Antares K# 063803 |
|-----------------------------------|-----------------------|--------------------------|
| ▪ 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) | √ | √ |
| Output Display Standard (Track 3) | √ | √ |
| Patient Contact Materials | Tested to ISO 10993-1 | Tested to ISO 10993-1 |
| UL 60601-1 Certified | √ | √ |

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

The device has 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.

Since the S2000 uses 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 S2000 is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

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

JUN 30 2011

Re: K111674
Trade/Device Name: S2000TM Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX and OBJ
Dated: June 14, 2011
Received: June 15, 2011

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 S2000TM Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

| | |
|-----------------------------|--|
| <u>CW2</u> | <u>6C1HD Curved Array</u> |
| <u>CW5</u> | <u>4V1 Phased Array</u> |
| <u>EC9-4 Curved Array</u> | <u>10V4 Phased Array</u> |
| <u>9L4 Linear Array</u> | <u>14L5 SP Linear Array</u> |
| <u>14L5 Multi-D Array</u> | <u>7CF2 Curved Array Mechanical 3D</u> |
| <u>14L5BV Multi-D Array</u> | <u>9EVF4 Curved Array</u> |
| <u>4P1 Phased Array</u> | <u>V5Ms Multiplane TEE</u> |
| <u>6C2 Curved Array</u> | <u>17L5HDS Linear Array</u> |
| <u>4C1 Curved Array</u> | <u>18L6 HD Linear Array</u> |

8V3 Phased Array
4V1c Phased Array
6L3
EV9C4

V7M TEE
AcuNav 8F Ultrasound Catheter
AcuNav 10F Ultrasound Catheter

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 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

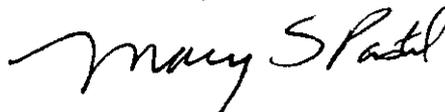
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

1.3 Indications for Use

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

Device Name: S2000™ Diagnostic Ultrasound System

Indications for Use:

The S2000™ 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.

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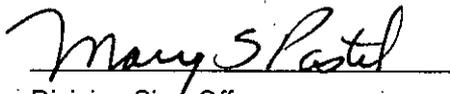
Prescription Use X
(Part 21CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K111674

Page 1 of _____

1.3 Indications for Use Forms

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **ACUSON S2000 Ultrasound System**
 Intended Use: **Ultrasound 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 2,3,4,5,7,8,10, 11, 13 |
| Abdominal | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11, 13, 16 |
| Intraoperative (Note 9) | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11, 14 |
| Intraoperative Neurological | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11, 14 |
| Pediatric | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11 |
| Small Organ (Note 1) | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11,14, 16 |
| Neonatal Cephalic | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10 |
| Adult Cephalic | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10 |
| Cardiac | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,6,7,8,10,15 |
| Trans-esophageal | | P | P | P | P | P | P | | BMDC | Note 4 |
| Transrectal | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11,14 |
| Transvaginal | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11 |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,6,7,8,10, 11,14,15 |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11,14 |
| Musculo-skeletal Superficial | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11,14 |
| Other (specify) Neonatal Cardiac | | P | P | P | P | P | P | | BMDC | Note 3,4,6, 10 |

N = new indication; P = previously cleared by FDA K063085, K063803, K072786, K081148, K082142, K090334, K093812

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 6 Cadence contrast agent imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging
- Note 9 For example: vascular, abdominal
- Note 10 Clarify VE vascular enhancement technology
- Note 11 Advanced Sieclear spatial compounding
- Note 13 STIC
- Note 14 eSie™ Touch elasticity imaging / FTI
- Note 15 AHP
- Note 16 Custom Tissue Imaging

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

Mary Stedil
 (Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: CW2 Probe for use with ACUSON S2000
 Intended Use: Ultrasound 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 | | | | | |
| Abdominal | | | | | P | | | | | |
| Intraoperative (Note 9) | | | | | P | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | P | | | | | |
| Small Organ (Note 1) | | | | | P | | | | | |
| Neonatal Cephalic | | | | | P | | | | | |
| Adult Cephalic | | | | | P | | | | | |
| Cardiac | | | | | P | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | P | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | P | | | | | |
| Musculo-skeletal Superficial | | | | | P | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA K# 063803, K072786, K081148, K082142, K090334, , K093812

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 9 For example: vascular, abdominal

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

Mary Stahl
 (Division Sign-Off)

Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111674

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: CW5 Probe for use with ACUSON S2000
 Intended Use: Ultrasound 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 | | | | | |
| Abdominal | | | | | P | | | | | |
| Intraoperative (Note 9) | | | | | P | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | P | | | | | |
| Small Organ (Note 1) | | | | | P | | | | | |
| Neonatal Cephalic | | | | | P | | | | | |
| Adult Cephalic | | | | | P | | | | | |
| Cardiac | | | | | P | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | P | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | P | | | | | |
| Musculo-skeletal Superficial | | | | | P | | | | | |
| Other (specify) | | | | | | | | | | |

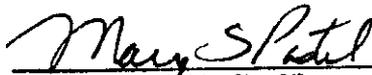
N = new indication; P = previously cleared by FDA K# 063803, K072786, K081148, K082142, K090334, , K093812

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 9 For example: vascular, abdominal

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)



(Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111674

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

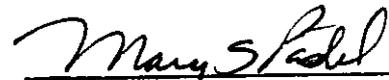
Device Name: EC9-4 Curved Array Transducer for use with ACUSON S2000
 Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

| 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 | | BMDC | Note 2,3,4,5,7,8,10, 11 |
| Abdominal | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,6,,7,8,10, 11, |
| Intraoperative Abdominal | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (Note 1) | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11,14 |
| Neonatal Cephalic | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10 |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | P | P | P | | P | P | | BMDC | Note 2,3,4,5, 6, 7,8,10, 11,14 |
| Transvaginal | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11 |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA K# 063803, K072786, K081148, K082142, K090334, K093812

Additional Comments:

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 6 Cadence contrast agent imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging
- Note 10 Clarify VE vascular enhancement technology
- Note 11 Advanced Sieclear spatial compounding
- Note 14 eSie™ Touch elasticity imaging / FTI


 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111674

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

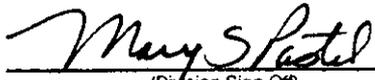
Device Name: 9L4 Linear Array Transducer for use with ACUSON S2000
 Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

| 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 | | BMDC | Note 2,3,4,5,7,8,10, 11 |
| Abdominal | | | | | | | | | | |
| Intraoperative Abdominal | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11 |
| Small Organ (Note 1) | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,6,7,8,10, 11,14, 16 |
| Neonatal Cephalic | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11 |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | P | P | P | | P | P | | BMDC | Note 15 |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,6, 7,8,10, 11, 14,15 |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,6,7,8,10, 11, 14 |
| Musculo-skeletal Superficial | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,6,7,8,10, 11, 14 |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812

Additional Comments:

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 6 Cadence contrast agent imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging
- Note 10 Clarify VE vascular enhancement technology
- Note 11 Advanced Sieclear spatial compounding
- Note 14 eSie™ Touch elasticity imaging / FTI
- Note 15 AHP
- Note 16 Custom Tissue Imaging


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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

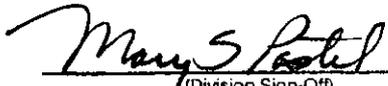
Device Name: 14L5 Multi-D Array Transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

| 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 Abdominal | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (Note 1) | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10,11,14,16 |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,6,7,8,10,11,14 |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10,11,14 |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812

Additional Comments:

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 6 Cadence contrast agent imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging
- Note 10 Clarify VE vascular enhancement technology
- Note 11 Advanced Sieclear spatial compounding
- Note 14 eSie™ Touch elasticity imaging / FTI
- Note 16 Custom Tissue Imaging


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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 14L5BV Multi-D Array Transducer for use with ACUSON S2000
 Intended Use: Ultrasound 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 Abdominal | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (Note 1) | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10, 11, 14, 16 |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA K# 081148, K093812

Additional Comments:

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 6 Cadence contrast agent imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging
- Note 10 Clarify VE vascular enhancement technology
- Note 11 Advanced Sieclear spatial compounding
- Note 14 eSie™ Touch elasticity imaging / FTI
- Note 16 Custom Tissue Imaging

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 4P1 Phased Array Transducer for use with ACUSON S2000
 Intended Use: Ultrasound 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 2,3,4,5,7,8,10 |
| Abdominal | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10 |
| Intraoperative Abdominal | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10 |
| Cardiac | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,6,7,8,10 |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA K# 063803, K072786, K081148, K082142, K090334, K093812

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 6 Cadence contrast agent imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging
- Note 10 Clarify VE vascular enhancement technology


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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 6C2 Curved Array Transducer for use with ACUSON S2000
Intended Use: Ultrasound 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 | | BMDC | Note 2,3,4,5,7,8,10,11 |
| Abdominal | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10,11,14,16 |
| Intraoperative Abdominal | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10,11 |
| Small Organ | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10,11 |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging
- Note 10 Clarify VE vascular enhancement technology
- Note 11 Advanced Sieclear spatial compounding
- Note 14 eSie™ Touch elasticity imaging / FTI
- Note 16 Custom Tissue Imaging

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

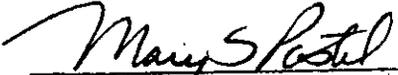
Device Name: 4C1 Curved Array Transducer for use with ACUSON S2000
 Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

| 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 2,3,4,5,7,8,10, 11 |
| Abdominal | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,6,7,8, 10, 11, 14, 16 |
| Intraoperative Abdominal | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ | | P | P | P | P | P | P | | BMDC | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | P | P | P | P | P | P | | BMDC | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | P | P | P | P | P | P | | BMDC | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 6 Cadence contrast agent imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging
- Note 10 Clarify VE vascular enhancement technology
- Note 11 Advanced Sieclear spatial compounding
- Note 14 eSie™ Touch elasticity imaging / FTI
- Note 16 Custom Tissue Imaging


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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 6C1HD Curved Array Transducer for use with ACUSON S2000
 Intended Use: Ultrasound 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 2,3,4,5,7,8,10,11 |
| Abdominal | | N | N | N | N | N | N | | BMDC | Note 2,3,4,5,6,7,8,10,11,14,16 |
| Intraoperative Abdominal | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ | | N | N | N | N | N | N | | BMDC | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | N | N | N | N | N | N | | BMDC | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | N | N | N | N | N | N | | BMDC | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA K#

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 6 Cadence contrast agent imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging
- Note 10 Clarify VE vascular enhancement technology
- Note 11 Advanced Sieclear spatial compounding
- Note 14 eSie™ Touch elasticity imaging / FTI
- Note 16 Custom Tissue Imaging

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

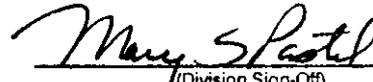
Device Name: 4V1 Phased Array Transducer for use with ACUSON S2000
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

| 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 | | BMDC | Note 2,3,4,5,7,8,10 |
| Abdominal | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10,14,16 |
| Intraoperative Abdominal | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging
- Note 10 Clarify VE vascular enhancement technology
- Note 11 Advanced Sieclear spatial compounding
- Note 14 eSie™ Touch elasticity imaging / FTI
- Note 16 Custom Tissue Imaging


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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 10V4 Phased Array Transducer for use with ACUSON S2000
 Intended Use: Ultrasound 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 2,3,4,5,7,8,10 |
| Abdominal | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10 |
| Intraoperative Abdominal | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10 |
| Small Organ | | | | | | | | | | |
| Neonatal Cephalic | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10 |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | P | P | P | P | P | P | | BMDC | Note 3,4 |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10 |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging
- Note 10 Clarify VE vascular enhancement technology

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 14L5 SP Linear Array Transducer for use with ACUSON S2000
 Indications For 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 9) | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10 |
| Intraoperative Neurological | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10,11 |
| Pediatric | | | | | | | | | | |
| Small Organ (Note 1) | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10,11,14,16 |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | P | P | P | | P | P | | BMDC | Note 15 |
| Transesophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,6,7,8,10,11,14,15 |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10,11,14 |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812

Additional Comments:

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 6 Cadence contrast agent imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging
- Note 9 For example: vascular, abdominal
- Note 10 Clarify VE vascular enhancement technology
- Note 11 Advanced Sieclear spatial compounding
- Note 14 eSie™ Touch elasticity imaging / FTI

- Note 15 AHP
- Note 16 Custom Tissue Imaging

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510K K111674

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 7CF2 Curved array mechanical 3D transducer for use with ACUSON S2000
 Intended Use: Ultrasound 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 | | BMDC | Note 2,3,4,5,7,8,10,11,13 |
| Abdominal | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10,11,13 |
| Intraoperative Abdominal | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA K# 063803, K072786, K081148, K082142, K090334, K093812

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging
- Note 10 Clarify VE vascular enhancement technology
- Note 11 Advanced Sieclear spatial compounding
- Note 13 STIC

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 9EVF4 Curved Array Transducer for use with ACUSON S2000
 Intended Use: Ultrasound 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 | | BMDC | Note 2,3,4,5,7,8, 10,11, 13 |
| Abdominal | | | | | | | | | | |
| Intraoperative Abdominal | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ | | | | | | | | | | |
| Neonatal Cephalic | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8, 10,11 |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8, 10,11 |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FOA K# 063803, K072786, K081148, K082142, K090334, K093812

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging
- Note 10 Clarify VE vascular enhancement technology
- Note 11 Advanced Sieclear spatial compounding
- Note 13 STIC

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: V5Ms Multiplane TEE Transducer for use with ACUSON S2000
 Intended Use: Ultrasound 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 Abdominal | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | P | P | P | P | P | P | | BMDC | Note 4 |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA K# 063803, K072786, K081148, K082142, K090334, K093812

Additional Comments:
 Note 4 Tissue Equalization Technology

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

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510K 5111674

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 17L5HDS Linear Array Transducer for use with ACUSON S2000
 Intended Use: Ultrasound 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 Abdominal | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (Note 1) | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10,11,14 |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10,11,14 |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10,11,14 |
| Musculo-skeletal Superficial | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10,11,14 |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA K# 063085, K072786, K082142, K090334 , K093812

Additional Comments:

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scapa real-time 3D imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging
- Note 10 Clarify VE vascular enhancement technology
- Note 11 Advanced Sieclear spatial compounding
- Note 14 eSie™ Touch elasticity imaging / FTI

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 18L6 HD Linear Array Transducer for use with ACUSON S2000
 Intended Use: Ultrasound 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 Abdominal | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (Note 1) | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10,11,14, 16 |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | P | P | P | | P | P | | BMDC | Note 15 |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10,11,14,15 |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10,11,14 |
| Musculo-skeletal Superficial | | P | P | P | | P | P | | BMDC | Note 2,3,4,5,7,8,10,11,14 |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA K081148, K082142, K090334, K093812

Additional Comments:

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging
- Note 10 Clarify VE vascular enhancement technology
- Note 11 Advanced Sieclear spatial compounding
- Note 14 eSie™ Touch elasticity imaging / FTI

- Note 15 AHP
- Note 16 Custom Tissue Imaging

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

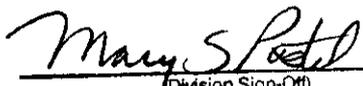
Device Name: 8V3 Phased Array Transducer for use with ACUSON S2000
 Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

| 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 2,3,4,5,7,8,10 |
| Abdominal | | | | | | | | | | |
| Intraoperative Abdominal | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10 |
| Small Organ | | | | | | | | | | |
| Neonatal Cephalic | | P | P | P | P | P | P | | BMDC | Note 2,3,4,5,7,8,10 |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | P | P | P | P | P | P | | BMDC | Note 3,4,6 |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) Neonatal Cardiac | | P | P | P | P | P | P | | BMDC | Note 3,4,6 |

N = new indication; P = previously cleared by FDA K# 063085, K072786, K081148, K082142, K090334, K093812

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 6 Cadence contrast agent imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging
- Note 10 Clarify VE vascular enhancement technology


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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 4V1c Phased Array Transducer for use with ACUSON S2000
 Intended Use: Ultrasound 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 10 |
| Abdominal | | P | P | P | P | P | P | | BMDC | Note 2 3 4 5 7 8 10 |
| Intraoperative Abdominal | | P | P | P | P | P | P | | BMDC | Note 2 3 4 5 7 8 10 |
| Intraoperative Neurological | | P | P | P | P | P | P | | BMDC | Note 2 3 4 5 7 8 10 |
| Pediatric | | P | P | P | P | P | P | | BMDC | Note 2 3 4 5 7 8 10 |
| Small Organ | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | P | P | P | P | P | P | | BMDC | Note 2 3 4 5 7 8 10 |
| Cardiac | | P | P | P | P | P | P | | BMDC | Note 2 3 4 5 7 8 10 15 |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | P | P | P | P | P | P | | BMDC | Note 2 3 4 5 7 8 10 15 |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) Neonatal Cardiac | | P | P | P | P | P | P | | BMDC | Note 2 3 4 5 7 8 10 |

N = new indication; P = previously cleared by FDA K#'s 052410, 051139, 041319, 032114, 022567, 063085, K090334, K093812

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 6 Cadence contrast agent imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging
- Note 10 Clarify VE vascular enhancement technology
- Note 15 AHP

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: 6L3 Transducer for use with ACUSON S2000
 Intended Use: Ultrasound 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 10, 11 |
| Abdominal | | | | | | | | | | |
| Intraoperative Abdominal | | P | P | P | P | P | P | | BMDC | Note 2 3 4 5 7 8 10, 11 |
| Intraoperative Neurological | | P | P | P | P | P | P | | BMDC | Note 2 3 4 5 7 8 10, 11 |
| Pediatric | | | | | | | | | | |
| Small Organ | | P | P | P | P | P | P | | BMDC | Note 2 3 4 5 7 8 10, 11 |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | P | P | P | P | P | P | | BMDC | Note 2 3 4 5 7 8 10 15 |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | P | P | P | P | P | P | | BMDC | Note 2 3 4 5 7 8 10, 11 15 |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | P | P | P | P | P | P | | BMDC | Note 2 3 4 5 7 8 10, 11 |
| Musculo-skeletal Superficial | | P | P | P | P | P | P | | BMDC | Note 2 3 4 5 7 8 10, 11 |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA K#'s 052410, 051139, 041319, 032114, 022567, 002807, 973767, 063085, K090334, K093812

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 6 Cadence contrast agent imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging
- Note 10 Clarify VE vascular enhancement technology
- Note 11 Advanced Sieclear spatial compounding
- Note 15 AHP


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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: EV8C4 Transducer for use with ACUSON S2000
 Intended Use: Ultrasound 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 10 |
| Abdominal | | P | P | P | P | P | P | | BMDC | Note 2 3 4 5 7 8 10 |
| Intraoperative Abdominal | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | P | P | P | P | P | P | | BMDC | Note 2 3 4 5 6 7 8 10 |
| Transurethral | | | | | | | | | | |
| Intravascular | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (specify) | | | | | | | | | | |

N = new indication; P = previously cleared by FDA K #'s 052410, 051139, 041319, 032114, 022567, 002807, 973767, 063085, K090334, K093812

Additional Comments:

- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- Note 5 3-Scape real-time 3D imaging
- Note 6 Cadence contrast agent imaging
- Note 7 B&W SieScape panoramic imaging
- Note 8 Power SieScape panoramic imaging
- Note 10 Clarify VE vascular enhancement technology

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: V7M TEE Transducer for use with ACUSON S2000
 Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | A | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Color Velocity Imaging | Combined (Specify) | Harmonic Imaging | Other (Specify) |
|---------------------------------|---|---|---|-----|-----|---------------|---------------------------|------------------------|--------------------|------------------|-----------------|
| Ophthalmic | | | | | | | | | | | |
| Fetal | | | | | | | | | | | |
| Abdominal | | P | P | P | P | P | P | | P* | P | Note 4 |
| Intraoperative Abdominal | | | | | | | | | | | |
| Intraoperative Neurological | | | | | | | | | | | |
| Pediatric | | P | P | P | P | P | P | | P* | P | Note 4 |
| Small Organ (specify)** | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | |
| Cardiac | | P | P | P | P | P | P | | P* | P | Note 4 |
| Trans-esophageal | | P | P | P | P | P | P | | P* | P | Note 4 |
| Transrectal | | | | | | | | | | | |
| Transvaginal | | | | | | | | | | | |
| Transurethral | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | |
| Peripheral Vessel | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | |
| Other (specify) | | | | | | | | | | | |

P=previously cleared by the FDA under premarket notifications #K052410, #K051139, #K041319, #K032114, and #K022567, K093812

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler,

B+M+POWER DOPPLER, B+PWD+POWER DOPPLER, B+CWD+POWER DOPPLER, B+CLARIFY VE

- Note 2 Ensemble tissue harmonic imaging
- Note 4 Tissue Equalization Technology
- Note 10 Clarify VE vascular enhancement technology

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

Mary S. Pechel
 Division Sign-Off
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111674

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **AcuNav 8F Ultrasound Catheter for use with ACUSON S2000**
 Intended Use: Catheter is intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients.

| Clinical Application | Mode of Operation | | | | | | | | | |
|-------------------------------|-------------------|---|---|-----|-----|---------------|---------------------------|------------------------|--------------------|-------------------------|
| | A | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Color Velocity Imaging | Combined (Specify) | Other: Harmonic Imaging |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative (Vascular) | | | | | | | | | | |
| Intraoperative (Neurological) | | | | | | | | | | |
| Pediatric | | P | P | P | P | P | P | | P* | |
| Small Organ (Specify)** | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | P | P | P | P | P | P | | P* | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intra-Luminal | | P | P | P | P | P | P | | P* | |
| Peripheral Vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (Intra-Cardiac) | | P | P | P | P | P | P | | P* | |

P=Previously cleared by the FDA K992631, K033650, K042593, K071234, K093812

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler,

B+M+POWER DOPPLER, B+PWD+POWER DOPPLER, B+CWD+POWER DOPPLER

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

Mary Spotted
 (Division Sign-Off)

Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111674

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **AcuNav 10F Ultrasound Catheter for use with ACUSON S2000**
 Intended Use: **Catheter is intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients.**

| Clinical Application | Mode of Operation | | | | | | | | | |
|-------------------------------|-------------------|---|---|-----|-----|---------------|---------------------------|------------------------|--------------------|-------------------------|
| | A | B | M | PWD | CWD | Color Doppler | Power (Amplitude) Doppler | Color Velocity Imaging | Combined (Specify) | Other: Harmonic Imaging |
| Ophthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intraoperative (Vascular) | | | | | | | | | | |
| Intraoperative (Neurological) | | | | | | | | | | |
| Pediatric | | P | P | P | P | P | P | | P* | |
| Small Organ (Specify)** | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | P | P | P | P | P | P | | P* | |
| Trans-esophageal | | | | | | | | | | |
| Transrectal | | | | | | | | | | |
| Transvaginal | | | | | | | | | | |
| Transurethral | | | | | | | | | | |
| Intra-Luminal | | P | P | P | P | P | P | | P* | |
| Peripheral Vessel | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-skeletal Conventional | | | | | | | | | | |
| Musculo-skeletal Superficial | | | | | | | | | | |
| Other (Intra-Cardiac) | | P | P | P | P | P | P | | P* | |

P=Previously cleared by the FDA K992631, K033650, K042593, K071234, , K093812

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler,

B+M+POWER DOPPLER, B+PWD+POWER DOPPLER, B+CWD+POWER DOPPLER

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Part 21CFR 801 Subpart D)

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510K K111674