K093812

510(k) Summary
Prepared December 28, 2009

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

MAR - 3 2010

Contact Person: Shelly Pearce
Telephone: (650) 694-5988
Fax: (650) 694-5580

Submission Date: December 1, 2009

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

A. Legally Marketed Predicate Devices

The Acuson S2000™ Ultrasound System is substantially equivalent to the Acuson Antares Ultrasound System.

B. Device Description:

The Acuson S2000™ has been designed to meet the following product safety standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
  - EN/IEC 60601-1
  - EN/IEC 60601-1-1
  - EN/IEC 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

C. 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".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR - 3 2010

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

Re: K093812
Trade/Device Name: ACUSON S2000™ Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: February 8, 2010
Received: February 16, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the ACUSON S2000™ Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

CW2	4C1 Curved Array
CW5	4V1 Phased Array
EC9-4 Curved Array	10V4 Phased Array
9L4 Linear Array	14L5 SP Linear Array
14L5 Multi-D Array	7CF2 Curved Array Mechanical 3D
14L5BV Multi-D Array	9EVF4 Curved Array
4P1 Phased Array	V5Ms Multiplane TEE
6C2 Curved Array	17L5HDS Linear Array

18L6 HD Linear Array
8V3 Phased Array
4V1c Phased Array
6L3

EV8C4
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" (21CFR 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,

Donald St. Pierre
Acting 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.

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".

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

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093812

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	
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	Note2,3,4,5,6,7,8,10, 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

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

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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Prescription Use (Per 21 CFR 801.10

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

Additional Comments:

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

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Prescription Use (Per 21 CFR 801.109)

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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

Additional Comments:

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

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Prescription Use (Per 21 CFR 801.109)

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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

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

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Prescription Use (Per 21 CFR 801.109)

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

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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Prescription Use (Per 21 CFR 801.109)

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

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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Prescription Use (Per 21 CFR 801.109)

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

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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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
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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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

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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510K K093812

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Prescription Use (Per 21 CFR 801.109)

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	Note2,3,4,5,6,7,8, 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

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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Prescription Use (Per 21 CFR 801.109)

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

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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Prescription Use (Per 21 CFR 801.109)

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

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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510K 1609381 2

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	Note2,3,4,5,6 ,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

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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Prescription Use (Per 21 CFR 801.109)

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

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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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
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 FDA K# 063803, K072786, K081148, K082142, K090334

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

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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	
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

Additional Comments: n/a

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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

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

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Prescription Use (Per 21 CFR 801.109)

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

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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Prescription Use (Per 21 CFR 801.109)

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

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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Prescription Use (Per 21 CFR 801.109)

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

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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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
Abdominal										
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										
Small Organ		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10
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 15
Laparoscopic										
Musculo-skeletal Conventional		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10
Musculo-skeletal Superficial		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10
Other (specify)										

N = new indication; P = previously cleared by FDA K#'s 052410, 051139, 041319, 032114, 022567, 002807, 973767, 063085, K090334
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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Prescription Use (Per 21 CFR 801.109)

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

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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510K K093812

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Prescription Use (Per 21 CFR 801.109)

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		N	N	N	N	N	N		N*	N	Note 2 3 4 5 7 8 10
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		N	N	N	N	N	N		N*	N	Note 2 3 4 5 7 8 10
Small Organ (specify)**											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N	N	N	N		N*	N	Note 2 3 4 5 7 8 10 15
Trans-esophageal		N	N	N	N	N	N		N*	N	Note 2 3 4 5 7 8 10
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.

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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Prescription Use (Per 21 CFR 801.109)

510K K093812

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.

	Mode of Operation									
Clinical Application	**A**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Color Velocity Imaging**	**Combined (Specify)**	**Other: Harmonic Imaging**
Ophtalmic										
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.

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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510K K093812

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.

	Mode of Operation									
Clinical Application	**A**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Color Velocity Imaging**	**Combined (Specify)**	**Other: Harmonic Imaging**
Ophtalmic										
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.

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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