K093817

S2000 Ultrasound System 510(k) Submission

# 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: Review Category: Tier II Classification Panel: Radiology

Ultrasonic Pulsed Doppler Imaging System FR # 892.1550 Ultrasonic Pulsed Echo Imaging System

FR # 892.1560

Product Code 90-IYN 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
- AlUM/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".



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 25<sup>th</sup> 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 CW5 EC9-4 Curved Array 9L4 Linear Array 14L5 Multi-D Array 14L5BV Multi-D Array 4P1 Phased Array 6C2 Curved Array 4C1 Curved Array
4V1 Phased Array
10V4 Phased Array
14L5 SP Linear Array
7CF2 Curved Array Mechanical 3D
9EVF4 Curved Array
V5Ms Multiplane TEE
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 <u>Federal Register</u>.

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 <a href="http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm">http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm</a> 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 <a href="http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm">http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</a> 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 UseX (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter U (21 CFR 801 Subpa	
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Concurrence of	CDRH, Office of	Device Evaluation (ODE)	DIVD
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Office of In Vitro Diagnostic Device Evaluation and Safety

610K 6093812

## 1.3 Indications for Use Forms

# Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: Intended Use:

**ACUSON S2000 Ultrasound System** 

Ultrasound imaging or fluid flow analysis of the human body as follows:

					<u></u>	M	lode of Oper	ation		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic			I							
Fetal		Р	Р	Р	Р	Р	Р		вмос	Note 2,3,4,5,7,8,10, 11, 13
Abdominal		Р	Р	Р	Р	Ρ	P		вмос	Note 2,3,4,5,7,8,10, 11, 13, 16
Intraoperative (Note 9)		P	Р	Р	P	<u>a</u>	Р		BMDC	Note 2,3,4,5,7,8,10, 11, 14
Intraoperative Neurological		Р	Р	Р		<u>-</u>	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14
Pediatric		Р	Р	Р	Р	P	Р		BMDC	Note 2,3,4,5,7,8,10, 11
Small Organ (Note 1)		Р	Р	Р	P	Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11,14, 16
Neonatal Cephalic		Р	Ρ	Ρ	Р	P	Р		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic		Ρ	Р	Р	Р	P	Р		BMDC	Note 2,3,4,5,7,8,10
Cardiac		Р	P	Р	Р	P	Р	·	BMDC	Note 2,3,4,5,6,7,8,10,15
Trans-esophageal		Р	Р	Р	Р	Р	Р		BMDC	
Transrectal		Р	P	Р		Р	Р	•	вмос	Note 2,3,4,5,7,8,10, 11,14
Transvaginal		Р	Ρ	P		P "	Р		BMDC	Note 2,3,4,5,7,8,10,
Transurethral										
Intravascular										
Peripheral vessel		P	Φ.	P	Р	Р	Р		BMDC	Note2,3,4,5,6,7,8,10, 11,14,15
Laparoscopic										,
Musculo-skeletal Conventional		Р	Р	Р	Р	Р	Р		вмос	Note 2,3,4,5,7,8,10, 11,14
Musculo-skeletal Superficial		Р	Р	P	Р	Р	Р		вмрс	Note 2,3,4,5,7,8,10, 11,14
Other (specify) Neonatal Cardiac		P	P	P	P	Р	Р		BMDC	Note 3,4,6

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

Note 1	For example	e: breast, test	es, thyroid, pen	is, 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:

		Mode of Operation											
Clinical Application	А	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)			
Ophthalmic													
Fetal					Р								
Abdominal					Р								
Intraoperative (Note 9)					Р								
Intraoperative Neurological													
Pediatric					Р								
Small Organ (Note 1)				ļ <u>-</u>	Р								
Neonatal Cephalic					Ρ.								
Adult Cephalic					Ρ_								
Cardiac					P	<u> </u>			<u> </u>				
Trans-esophageal						<u></u>				<u> </u>			
Transrectal				<u> </u>	<u> </u>								
Transvaginal		<u> </u>							<u> </u>	<del>_</del>			
Transurethral					<u> </u>		<u> </u>		<u> </u>				
Intravascular		<u> </u>	<u> </u>		<u> </u>								
Peripheral vessel					Р			<u></u>	ļ				
Laparoscopic		<u> </u>											
Musculo-skeletal Conventional					Р								
Musculo-skeletal Superficial					Р								
Other (specify)								<u> </u>	<u>j</u>				

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

Additional Cor
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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 Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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510K 14093812

510 (k) Number (if known):

Device Name:

CW5 Probe for use with ACUSON \$2000

Intended Use:

Ultrasound imaging or fluid flow analysis of the human body as follows:

						M	ode of Opera	ation		
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal					Р					
Abdominal	1				Р					
Intraoperative (Note 9)					Р			-		
Intraoperative Neurological										
Pediatric					Р			<del></del> -		
Small Organ (Note 1)					Р					
Neonatal Cephalic					Р			· -		
Adult Cephalic					Р					
Cardiac					Р					
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular								•		
Peripheral vessel					Р		·			
Laparoscopic						4.				
Musculo-skeletal Conventional					Р	-				
Musculo-skeletal Superficial					Р					
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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Concurrence of CDRH, Office of Device: Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

15093812

510 (k) Number (if known):

Device Name: Intended Use: EC9-4 Curved Array Transducer for use with ACUSON \$2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Ρ	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11
Abdominal		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,6,,7,8,10, 11,
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric						-				
Small Organ (Note 1)		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11,14
Neonatal Cephalic		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac									<b> </b>	
Trans-esophageal										
Transrectal		Р	P	Р		P	Р		вмос	Note 2,3,4,5, 6, 7,8,10, 11,14
Transvaginal		ρ	Р	Р		Р	Р		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 Comme	nts:
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Note 1 For example: breast, testes, thyroid, penis, prostate, etc.

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Tissue Equalization Technology Note 4

3-Scape real-time 3D imaging Note 5

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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510 (k) Number (if known):

Device Name: Intended Use: 9L4 Linear Array Transducer for use with ACUSON S2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

					<del></del>	····	Mode of C	peration		
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8,10, 11
Abdominal					İ					·
Intraoperative Abdominal									_	
Intraoperative Neurological						-				
Pediatric		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11
Small Organ (Note 1)		Р	Р	Р		Р	P		BMDC	Note 2,3,4,5,6,7,8,10, 11,14, 16
Neonatal Cephalic		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11
Adult Cephalic										
Cardiac		Р	Р	P		P	Р		BMDC	Note 15
Trans-esophageal	Ĭ									
Transrectal										
Transvaginal	}									
Transurethral				<u> </u>			1			
Intravascular					<u> </u>					
Peripheral vessel		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,6, 7,8,10, 11, 14,15
Laparoscopic										
Musculo-skeletal Conventional		Р	Р	Р		Р	P		вмос	Note 2,3,4,5,6,7,8,10, 11, 14
Musculo-skeletal Superficial		Р	Р	Р		Р	Р		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:**

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Note	For example:	Dreast.	lestes.	HIVIOIU.	Deilio.	prostate.	CIC.

Note 2 Ensemble tissue harmonic imaging

SieClear multi-view spatial compounding Note 3

Note 4 Tissue Equalization Technology

3-Scape real-time 3D imaging Note 5

Note 6 Cadence contrast agent imaging

B&W SieScape panoramic imaging Note 7

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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510 (k) Number (if known):

Device Name: Intended Use:

14L5 Multi-D Array Transducer for use with ACUSON \$2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

***		Mode of Operation										
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic												
Fetal												
Abdominal								٠				
Intraoperative Abdominal												
Intraoperative Neurological												
Pediatric									_			
Small Organ (Note 1)		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8,10, 11, 14, 16		
Neonatal Cephalic	Ì											
Adult Cephalic												
Cardiac												
Trans-esophageal				<u> </u>								
Transrectal					l							
Transvaginal		Ĺ					!					
Transurethral												
Intravascular												
Peripheral vessel		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,6, 7,8,10, 11, 14		
Laparoscopic												
Musculo-skeletal Conventional		Р	P	P		Р	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

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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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510K 15093812

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510 (k) Number (if known):

Device Name: Intended Use: 14L5BV Multi-D Array Transducer for use with ACUSON S2000 Ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation									
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic											
Fetal											
Abdominal						·					
Intraoperative Abdominal Intraoperative											
Neurological	ļ										
Pediatric											
Small Organ (Note 1)		Р	Р	Р		Р	Р		ВМОС	Note 2,3,4,5,7,8,10, 11, 14, 16	
Neonatal Cephalic											
Adult Cephalic				<u> </u>							
Cardiac	<u></u>										
Trans-esophageal											
Transrectal											
Transvaginal				l.						<u> </u>	
Transurethral									<u>'</u>		
Intravascular		l .									
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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510K 6093812

510 (k) Number (if known):

Device Name: Intended Use: 4P1 Phased Array Transducer for use with ACUSON \$2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation									
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic						~				•	
Fetal		Р	P	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10	
Abdominal		Р	Ρ	Р	Р	P	Р		BMDC	Note 2,3,4,5,7,8,10	
Intraoperative Abdominal											
Intraoperative Neurological					_						
Pediatric			ļ								
Small Organ				<u> </u>	<u>.</u>						
Neonatal Cephalic											
Adult Cephalic		Р	Р	P	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10	
Cardiac		P	Р	Р	P	Р	Р		BMDC	Note 2,3,4,5,6,7,8,10	
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral			,						<u> </u>		
Intravascular									1		
Peripheral vessel											
Laparoscopic							ļ				
Musculo-skeletal Conventional											
Musculo-skeletai Superficial											
Other (specify)					<u> </u>			<u> </u>	<u> </u>		

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

Note 2 Ens	emble tissu	e harmon	ic imaging	J
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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 Device Evaluation (QDE)

Prescription Use (Per 21 CFR 801.109)

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

510K K093812

510 (k) Number (if known):

Device Name: Intended Use:

6C2 Curved Array Transducer for use with ACUSON \$2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation									
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic							,				
Fetal		P	Р	Р	ļ	Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11	
Abdominal		Р	Ρ	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11, 14, 16	
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10,	
Small Organ											
Neonatal Cephalic											
Adult Cephalic											
Cardiac						-					
Trans-esophageal						·				<u>"</u>	
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11	
Laparoscopic		i ———									
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

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

Additional	Comments:
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- Note 2 Ensemble tissue harmonic imaging
- Note 3 SieClear multi-view spatial compounding
- Note 4 Tissue Equalization Technology
- 3-Scape real-time 3D imaging Note 5
- Note 7 B&W SieScape panoramic imaging
- 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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Office of In Vitro Diagnostic Device Evaluation and Safety

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510 (k) Number (if known):

Device Name: Intended Use:

4C1 Curved Array Transducer for use with ACUSON S2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation									
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic											
Fetal		Ρ	Р	Р	Р	Р	Р		вмос	Note 2,3,4,5,7,8,10, 11	
Abdominal		Р	Р	Р	Р	Р	P		BMDC	Note2,3,4,5,6,7,8, 10, 11, 14, 16	
Intraoperative Abdominal											
Intraoperative Neurological		_									
Pediatric	1	_									
Small Organ		P	Р	Р	Р	Р	Р		BMDC		
Neonatal Cephalic			Ī						<u> </u>		
Adult Cephalic			-						T		
Cardiac		Р	P	Р	Р	Р	Р		BMDC		
Trans-esophageal											
Transrectal				T			,				
Transvaginal											
Transurethral				1							
Intravascular			[								
Peripheral vessel		Р	Р	Р	Р	Р	Р		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	: imagi	ing

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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Office of In Vitro Diagnostic Device Evaluation and Safety

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510 (k) Number (if known):

Device Name: Intended Use:

4V1 Phased Array Transducer for use with ACUSON S2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation								
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8,10
Abdominal		Р	Р	Р		P	Р		вмос	Note 2,3,4,5,7,8,10, 14, 16
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic		Ī		l						
Adult Cephalic										
Cardiac				l						
Trans-esophageal										
Transrectal										
Transvaginal					ĺ		'			
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional									<u> </u>	
Musculo-skeletal Superficial										
Other (specify)										

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

# Additional Comments:

ľ	٧c	ite	2	Ensemb	ole tissu	e l	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 Device Evaluation: (QDE) - CITY |

510 (k) Number (if known):

Device Name: Intended Use:

10V4 Phased Array Transducer for use with ACUSON \$2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation									
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic							1				
Fetal		P	Р	P	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10	
Abdominal		Р	P	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10	
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric	<u> </u>	Ρ	Р	Р	Ρ	Р	Р		BMDC	Note 2,3,4,5,7,8,10	
Small Organ											
Neonatal Cephalic		P	Р	P	Р	P	Р		BMDC	Note 2,3,4,5,7,8,10	
Adult Cephalic											
Cardiac		Р	Р	Р	Ð	Р	P	ľ	BMDC	Note 3,4	
Trans-esophageal											
Transrectal											
Transvaginal	· ·										
Transurethral									·		
Intravascular											
Peripheral vessel		Р	Р	Р	Р	Р	Р		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
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SieClear multi view spatial compounding Note 3

Note 4 Tissue Equalization Technology

3-Scape real-time 3D imaging Note 5

B&W SieScape panoramic imaging Note 7

Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off) Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510 (k) Number (if known):

Device Name: Indications For Use:

14L5 SP Linear Array Transducer for use with ACUSON \$2000 Diagnostic imaging or fluid flow analysis of the human body as follows:

		Mode of Operation								
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal	L	<u> </u>			-					
Abdominal										
Intraoperative (Note 9)		Р	Ρ	Р		Р	Р		ВМДС	Note 2,3,4,5,7,8,10
Intraoperative Neurological		Р	₽	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11
Pediatric										
Small Organ (Note 1)		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11,14, 16
Neonatal Cephalic		l								
Adult Cephalic										
Cardiac		P	Р	Р		Р	. Р		BMDC	Note 15
Transesophageal										
Transrectal										
Transvaginal										
Transurethral			•							
Intravascular										
Peripheral vessel		₽	Р	Р		Р	Р		BMDC	Note2,3,4,5,6 ,7,8,10, 11,14,15
Laparoscopic										
Musculo-skeletal Conventional		P	Р	Р		Р	Р		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.
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Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Tissue Equalization Technology Note 4

Note 5 3-Scape real-time 3D imaging

Cadence contrast agent imaging Note 6

Note 7 B&W SieScape panoramic imaging

Power SieScape panoramic imaging Note 8 For example: vascular, abdominal Note 9

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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510 (k) Number (if known):

Device Name: Intended Use: 7CF2 Curved array mechanical 3D transducer for use with ACUSON S2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation										
Clinical Application	A	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic												
Fetal		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11,13		
Abdominal		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8,10, 11, 13		
Intraoperative Abdominal												
Intraoperative Neurological									_			
Pediatric	1									,		
Small Organ					T							
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Trans-esophageal												
Transrectal												
Transvaginal												
Transurethral	T					[						
Intravascular												
Peripheral vessel			1									
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 imagi	ing
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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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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093812

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510 (k) Number (if known):

Device Name: Intended Use: 9EVF4 Curved Array Transducer for use with ACUSON S2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic											
Fetal		Р	Ρ	P		Р	Р		BMDC	Note 2,3,4,5,7,8, 10,11	
Abdominal	·										
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ				•							
Neonatal Cephalic		Р	Р	Р	i	Р	P		вмос	Note 2,3,4,5,7,8, 10,11	
Adult Cephalic	-	· · · · ·									
Cardiac					Ī.						
Trans-esophageal										• •	
Transrectal											
Transvaginal		Р	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8, 10,11	
Transurethral					Ī						
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

Addition	al Comments:	/4.4
Note 2	Ensemble tissue harmonic imaging	AH <del>X 1) </del>
Note 3	SieClear multi-view spatial compounding	(Division Sign-Off)
Note 4	Tissue Equalization Technology	Division of Radiological Devices
Note 5	3-Scape real-time 3D imaging	Office of In Vitro Diagnostic Device Evaluation and Safety
Note 7	B&W SieScape panoramic imaging	1/
Note 8	Power SieScape panoramic imaging	510K 15043812
Note 10	Clarify VE vascular enhancement technology	O TOR

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Note 11 Advanced Sieclear spatial compounding

510 (k) Number (if known):

Device Name: Intended Use:

V5Ms Multiplane TEE Transducer for use with ACUSON S2000 Ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation										
Clinical Application	Α	В	М	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	Р	Р	Р	Р	Р		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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Concurrence of CDRH, Office of Devices Evaluation (QDE)

Prescription Use (Per 21 CFR 801.109)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K <u>6093812</u>

510 (k) Number (if known):

Device Name: Intended Use: 17L5HDS Linear Array Transducer for use with ACUSON S2000 Ultrasound imaging or fluid flow analysis of the human body as follows:

						M	ode of Opera	ation		
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic							1			
Fetal										
Abdominal				· · · · · ·				-		
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		Р	Р	Р.		Р	Р		BMDC	Note 2,3,4,5,7,8,10 11,14
Neonatal Cephalic										
Adult Cephalic									<b> </b>	
Cardiac				<u> </u>			<u>-</u>			
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral	1									
Intravascular										
Peripheral vessel		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10 11,14
Laparoscopic				l						
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10 11,14
Musculo-skeletal Superficial		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10 11,14
Other (specify)			T	1						

N = new indication; P = previously cleared by FDA K# 063085, K072786, 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 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)
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Office of in Vitro Diagnostic Device Evaluation and Safety

510K 5093812

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510 (k) Number (if known):

Device Name: Intended Use:

18L6 HD Linear Array Transducer for use with ACUSON S2000 Ultrasound imaging or fluid flow analysis of the human body as follows:

						Me	ode of Opera	ation		
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	1									
Fetal										
Abdominal	1									
Intraoperative Abdominal						=	-	,		
Intraoperative Neurological										• • • • • • • • • • • • • • • • • • • •
Pediatric										
Small Organ (Note 1)		Р	Р	Р		Р	P		BMDC	Note 2,3,4,5,7,8,10, 11,14, 16
Neonatal Cephalic										
Adult Cephalic					_					
Cardiac		Р	Р	Р		P	Р		BMDC	Note 15
Trans-esophageal										
Transrectal					· .					
Transvaginal				<u> </u>						
Transurethral					·					
Intravascular		<u> </u>								
Peripheral vessel		P	Р	Р		Р	P		вмос	Note 2,3,4,5,7,8,10, 11,14,15
Laparoscopic										
Musculo-skeletal Conventional		P	Р	Р		Р	Р		вмос	Note 2,3,4,5,7,8,10, 11,14
Musculo-skeletal Superficial		P	P	P		Р	Р		BMDC	Note 2,3,4,5,7,8,10, 11,14
Other (specify)			l						1	

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

Additional	Comments:
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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

S2000 510(k) Submission

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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Office of In Vitro Diagnostic Device Evaluation and Safety

510K 1093812

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Concurrence of CDRH, Office of Device: Evaluation (QDE)

510 (k) Number (if known):

Device Name: Intended Use:

8V3 Phased Array Transducer for use with ACUSON \$2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation									
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic											
Fetal		Р	Р	P	P	Р	Р		BMDC	Note 2,3,4,5,7,8,10	
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		Р	Р	Р	P	Р	Р		BMDC	Note 2,3,4,5,7,8,10	
Small Organ											
Neonatal Cephalic		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10	
Adult Cephalic											
Cardiac		Р	Р	Р	Р	Р	Р		BMDC	Note 3,4,6	
Trans-esophageal			]								
Transrectal								_			
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic					i						
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify) Neonatal Cardiac		Р	Р	Р	Р	Р	Р		BMDC	Note 3,4,6	

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

### Additional Comments:

Note 2	Ensemble	tieeup	harmonic	imaging
INULOZ	Et 19 CITIDIO	แองนต	Haililonic	maymy

Note 3 SieClear multi-view spatial compounding

Tissue Equalization Technology Note 4

3-Scape real-time 3D imaging Note 5

Cadence contrast agent imaging Note 6

Note 7 **B&W SieScape panoramic imaging** 

Note 8 Power SieScape panoramic imaging Note 10 Clarify VE vascular enhancement technology

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510 (k) Number (if known):

Device Name: Intended Use: 4V1c Phased Array Transducer for use with ACUSON \$2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic											
Fetal		P	P	P	P	P	P	1	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	Р		BMDC	Note 2 3 4 5 7 8 10	
Intraoperative Neurological		P	P	Ŀ	Р	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	Р	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10	
Cardiac		Р	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10	
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) 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

SieClear multi-view spatial compounding Note 3

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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510 (k) Number (if known):

Device Name: Intended Use:

6L3 Transducer for use with ACUSON S2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application	А	В	М	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										<u> </u>	
Intraoperative Abdominal		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10	
Intraoperative Neurological		P	Р	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	Р	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	<del> </del>	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

SieClear multi-view spatial compounding Note 3

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Cadence contrast agent imaging Note 6 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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510 (k) Number (if known):

Device Name: Intended Use: EV8C4 Transducer for use with ACUSON S2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

-	Mode of Operation											
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic												
Fetal		Р	Р	Р	P	Р	Р		BMDC	Note 2 3 4 5 7 8 10		
Abdominal		Р	Р	Р	Р	Р	Р		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		Р	Р	P	Р	Р	Р		BMDC	Note 2 3 4 5 6 7 8 10		
Transurethral												
Intravascular									i —			
Peripheral vessel												
Laparoscopic												
Musculo-skeletal Conventional								"				
Musculo-skeletal Superficial												
Other (specify)						<u> </u>						

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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Concurrence of CDRH, Office of Device Evaluation (ODE)

510 (k) Number (if known):

Device Name: Intended Use:

V7M TEE Transducer for use with ACUSON \$2000

Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Ā	В	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	Other (Specify)
Ophthalmic	1									<del> </del>	
Fetal											<u></u>
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					<del></del>		<del> </del>				<del></del>
Adult Cephalic	-		•				1	-		ļ	
Cardiac		N	N	N	N	N	N		N*	N	Note 2 3 4 5 7 8 10
Trans-esophageal	<u> </u>	N	N	N	N	N	N		N*	N	Note 2 3 4 5 7 8 10
Transrectal					_						
Transvaginal		i								<u> </u>	
Transurethral								1			
Intravascular	1									<del>-</del>	<del>-</del>
Peripheral Vessel							<u> </u>			<del> </del>	
Laparoscopic	<b></b>							*			
Musculo-skeletal (Conventional)											
Musculo-skeletal (Superficial)											
Other (specify)									<u> </u>	<del>-</del>	

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

Additional	Comments:
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\*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+CWD+Color Doppler, B+PwD+Color Dopple

## 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 4 Tissue Equalization Technology

Note 10 Clarify VE vascular enhancement technology

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Prescription Use (Per 21 CFR 801.109) Office of I	(Division Sign-Off) Division of Radiological Devices In Vitro Diagnostic Device Evaluation and Safety

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	В	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		1											
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						1							
Conventional		<u> </u>			<u> </u>			ļ.,					
Musculo-skeletal					1								
Superficial		<del> </del>						ļ					
Other (Intra-Cardiac)	1	P	P	P	P	P	P		P*	1			

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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Prescription Use (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K KO938/2

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	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging			
Ophtalmic								i					
Fetal						1							
Abdominal													
Intraoperative (Vascular)								,					
Intraoperative (Neurological)													
Pediatric		P	P	P	P	P	P	·	P*	· · · · · · · · · · · · · · · · · · ·			
Small Organ (Specify)**													
Neonatal Cephalic					1								
Adult Cephalic								<u> </u>					
Cardiac		P	P	P	P	P	P	i	P*	1			
Trans-esophageal					_			· · · · · · · · · · · · · · · · · · ·	Ì				
Transrectal													
Transvaginal													
Transurethral			ļ										
Intra-Luminal		P	P	P	P _	P	P		P*				
Peripheral Vessel													
Laparoscopic													
Musculo-skeletal													
Conventional		ļ	<u> </u>										
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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