510(K) SUMMARY

KO63803 JAN - 5 2007

ACUSON ANTARES™ Diagnostic Ultrasound System

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

1. Submitted By:

Siemens Medical Solutions USA, Inc., Ultrasound Division 1230 Shorebird way Mountain View, CA 94043

Contact Person:

Michaela Mahl Regulatory Affairs Specialist Phone: (650) 694 5653 FAX: (650) 943 7053

Date Prepared:

12/01/2006

2. Proprietary Name:

ACUSON ANTARES™ Ultrasound System

Common/ Usual Name:

Diagnostic Ultrasound System with Accessories

Classification Name:

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

3. Predicate Device:

- K063138, 11/22/2006, ACUSON Antares[™] Diagnostic Ultrasound System
- K050034, 01/13/2005, SONOLINE Antares™ Diagnostic Ultrasound System
- K033196, 10/16/2003, SONOLINE Antares[™] with CLARIFY VE Diagnostic Ultrasound System

4. Device Description:

The ANTARES system is a multi-purpose diagnostic ultrasound system with accessories and proprietary software.

The ACUSON ANTARES has been designed to meet the following product safety standards:

- UL 60601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment

- NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
- EN 60601-1
- EN 60601-1-1
- EN 60601-1-2
- EN 60601-1-2-37
- EN 60601-1-4
- IEC 61157 Declaration of Acoustic Power
- ISO 10993 Biocompatibility
- The system's acoustic output is in accordance with ALARA principle (as low as reasonably achievable)

5. Intended Uses:

The Antares ultrasound imaging system is intended for the following applications: Abdominal, Intraoperative, Small Parts, Transcranial, OB/GYN, Cardiac, Intracardiac, Transesophageal, Pelvic, Neonatal/Adult Cephalic, Vascular, Intravascular, Musculoskeletal, Superficial Musculoskeletal, Great Vessel, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures that provide information that is used for clinical diagnosis purposes.

6. Technological Comparison to Predicate Device:

The ACUSON ANTARES™ is substantially equivalent to the predicate devices listed in paragraph 3 above. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures to aid in diagnosis.

End of 510(k) Summary



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

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

JAN - 5 2007

Re: K063803

Trade Name: ACUSON Antares Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: December 21, 2006 Received: December 22, 2006

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 Antares Diagnostic Ultrasound System as described in your premarket notification:



Transducer Model Number

<u>CW2</u>	PX4-1 Phased Array
CW5	CH6-2 Curved Array
C5-2 Curved Array	CH4-1 Curved Array
CX5-2 Curved Array	PH4-1 Phased Array
VF7-3 Linear Array	P10-4 Phased Array
EC9-4 Curved Array	VF13-5SP Linear Array
VFX9-4 Linear Array	C5F1 Curved Array Mechanical 3D
VF10-5 Linear Array	C7F2 Curved Array Mechanical 3D
VF13-5 Linear Array	EV9F4 Curved Array
VFX13-5 Multi-D Array	V5Ms Multiplane TEE

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <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 determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850 This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Andrew Kang (240) 276-3666.

Sincerely yours,

Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Janey C Brogdon

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

510 (k) Number (if known):

K063803

Device Name:

ACUSON Antares Ultrasound System

Intended Use:

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

i -	<u> </u>	Mode of Operation									
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic											
Fetal		Ъ	Р	Р	P	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 (Note 9)		P	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10	
Intraoperative Neurological		P	Ь	Р		P	Р		BMDC	Note 2,3,4,5,7,8,10	
Pediatric		<u>a</u>	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10	
Small Organ (Note 1)		Ρ	Ρ	Р	Р	Р	Р		ВМДС	Note 2,3,4,5,7,8,10	
Neonatal Cephalic		.	Р	P	Ρ	Р	Р		BMDC	Note 2,3,4,5,7,8,10	
Adult Cephalic		Р	Р	Р	P	Р	P		BMDC	Note 2,3,4,5,7,8,10	
Cardiac		α.	Р	Р	P	P.	Р		BMDC	Note 2,3,4,5,6,7,8,10	
Trans-esophageal		P	P	Р	Р	Р	Р	-	BMDC	Note 2,3,4,5,6,10	
Transrectal		Р	Р	Р		P	P		BMDC	Note 2,3,4,5,7,8,10	
Transvaginal		р,	Р	Р		P	P		BMDC	Note 2,3,4,5,7,8,10	
Transurethral										11010 210, 1101, 101, 10	
Intravascular								v.	- 		
Peripheral vessel		P	P	Р	Р	P	Р		BMDC	Note 2,3,4,5,7,8,10	
Laparoscopic											
Musculo-skeletal Conventional		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10	
Musculo-skeletal Superficial		P	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10	
Other (specify)											

N = new indication; P = previously cleared by FDA - K063138, K050034, K033196; E = added under Appendix E

Additional Comments:

Note 1	For example: breast,	testes.	thyroid.	nenis	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 (cardiac only)

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number

510 (k) Number (if known):

K063803

Device Name:

CW2 Probe for use with ACUSON Antares

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)					P					
Intraoperative Neurological						•		· · · ·		
Pediatric					P		 		 	······································
Small Organ (Note 1)					Р					
Neonatal Cephalic					Р				 	
Adult Cephalic					Р					
Cardiac					Р				 	· · · · · · · · · · · · · · · · · · ·
Trans-esophageal							† ···		 	
Transrectal		_				·			 	
Transvaginal									 	
Transurethral			-	1			!		 -	··-
Intravascular									 	· **
Peripheral vessel		ļ			P		 		 	
Laparoscopic									 	·
Musculo-skeletal Conventional					Р					
Musculo-skeletal Superficial										
Other (specify)					_					

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyrold, 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)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number

510 (k) Number (if known):

K063803

Device Name:

CW5 Probe for use with ACUSON Antares

Intended Use:

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	l	[
Fetal					P							
Abdominal					Р							
Intraoperative (Note 9)					Р							
Intraoperative Neurological												
Pediatric					Р							
Small Organ (Note 1)					Р							
Neonatal Cephalic					Р		<u> </u>	··				
Adult Cephalic					Р							
Cardiac			-		Р				<u> </u>			
Trans-esophageai									1			
Transrectal										- · · · · · · · · · · · · · · · · · · ·		
Transvaginal												
Transurethral									†			
Intravascular									† · · · · · · · · · · · · · · · · · · ·			
Peripheral vessel					Р				 -	· · · · · · · · · · · · · · · · · · ·		
Laparoscopic	1					.,			 			
Musculo-skeletal Conventional					P	•						
Musculo-skeletal Superficial												
Other (specify)		1		<u> </u>					 			

N = new indication; P = previously cleared by FDA - K050034; E = added under Appendix E

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)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices KOln 3803

510(k) Number_

510 (k) Number (if known):

K063803

Device Name: Intended Use:

Ultrasound Division

C5-2 Curved Array Transducer for use with ACUSON Antares

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

		Mode of Operation									
Clinical Application	A	В	М	PWD	CMD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic											
Fetal		Р	1	P		Р	Р		BMDC	Note 2,3,4,5,7,8,10	
Abdominal		Р	Р	P		Р	Р		вмос	Note 2,3,4,5,7,8,10	
Intraoperative Abdominal											
Intraoperative Neurological								· 			
Pediatric		P	р	Р		Р	P		BMDC	Note 2,3,4,5,7,8,10	
Small Organ								_			
Neonatal Cephalic											
Adult Cephalic]							
Cardiac				1							
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel	1	Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10	
Laparoscopic	T								-	= = 1 = 1 - 1 - 1 - 1 - 1 - 1	
Musculo-skeletal Conventional		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,10	
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

ľ	lote	2	Ensem	ble tissue	harmonic	imaging

SieClear multi-view spatial compounding Tissue Equalization Technology Note 3

Note 4

Note 5 3-Scape real-time 3D Imaging

Note 7 B&W SieScape panoramic imaging

Power SieScape panoramic imaging Note 8

Note 10 Clarify VE vascular enhancement technology

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number ___

K063803

510 (k) Number (if known):

K063803

Device Name: Intended Use:

CX5-2 Curved Array Transducer for use with ACUSON Antares 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		P	P		BMDC	Note 2,3,4,5,7,8,10	
Abdominal		P	Р	P		Р	P		BMDC	Note 2,3,4,5,7,8,10	
Intraoperative Abdominal										11000 2101410111,0110	
Intraoperative Neurological				:				•			
Pediatric		P	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,10	
Small Organ									-,,,,,,,	11010 2,0,4,0,7,0,10	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal			·								
Transvaginal								· · · · · · · · · · · · · · · · · · ·			
Transurethral		i —			<u>-</u>		i				
Intravascular											
Peripheral vessel		Ъ	Р	P		P	Р		BMDC	Note 2,3,4,5,7,8,10	
Laparoscopic									1000	13010 2,0,4,0,7,0,10	
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10	
Musculo-skeletal Superficial						,					
Other (specify)											

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 2	Ensemble	tissue	harmonic imagino	
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Note 3 SieClear multi-view spatial compounding

Tissue Equalization Technology Note 4

3-Scape real-time 3D imaging Note 5

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)

(Division Sign-Qff)

Division of Reproductive, Abdominal,

and Radiological Devices KO6 510(k) Number _

510 (k) Number (if known):

K063803

Device Name: Intended Use: VF7-3 Linear Array Transducer for use with ACUSON Antares Ultrasound imaging or fluid flow analysis of the human body as follows:

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

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 1	For example: brea	st, testes, t	hyroid, penis,	prostate, etc.
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Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D Imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number_

510 (k) Number (if known):

K063803

Device Name:

EC9-4 Curved Array Transducer for use with ACUSON Antares

Intended Use: Ultrasound Imaging or fluid flow analysis of the human body as follows:

					<u></u>	Me	ode of Opera	ation		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic					1					
Fetal		P	ıР	Р		Ρ	Р		BMDC	Note 2,3,4,5,7,8,10
Abdominal									5.0.50	11010 2101710110110
Intraoperative Abdominal						-				
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		þ	Р		BMDC	Note 2,3,4,5,7,8,10
Neonatal Cephalic		Р	Р	Р		Р	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										11010 2,0,17,0,17,0,10
Cardiac										······································
Trans-esophageal	١.									
Transrectal		Ρ	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10
Transvaginal		P	Ρ.	Р		P	Р		BMDC	Note 2,3,4,5,7,8,10
Transurethral									5	11010 2,0,7,0,1,0,10
Intravascular							-			
Peripheral vessel			-				 			
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 1	For example: brea	st testes thyroid	nenis 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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number_

510 (k) Number (if known):

K063803

Device Name: Intended Use: VFX9-4 Linear Array Transducer for use with ACUSON Antares 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		1								
Fetal		Р	P	Р		P	Р		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	Р	Р		P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										· · · · · · · · · · · · · · · · · · ·
Pediatric		Р	Р	Р		Р	Р	· · · · · ·	BMDC	Note 2,3,4,5,7,8,10
Small Organ (Note 1)		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10
Neonatal Cephalic		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic			-							
Cardiac										····
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										· ,
Intravascular		<u> </u>								
Peripheral vessel		P	P	P		Р	Р		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic									1	1-1-1-1-1-1-1-
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10
Musculo-skeletal Superficial		P	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

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

Ensemble tissue harmonic imaging Note 2

Note 3 SieClear multi-view spatial compounding

Tissue Equalization Technology Note 4

3-Scape real-time 3D imaging Note 5

Note 7 B&W SieScape panoramic imaging

Power SieScape panoramic imaging Note 8

Note 10 Clarify VE vascular enhancement technology

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number ___

510 (k) Number (if known):

K063803

Device Name: Intended Use: VF10-5 Linear Array Transducer for use with ACUSON Antares

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		Р	Р		BMDC	Note 2,3,4,5,7,8,10			
Abdominal		P	P	Р		P	P		BMDC	Note 2,3,4,5,7,8,10			
Intraoperative Abdominal										1100 2101 11011 10110			
Intraoperative Neurological					-								
Pediatric		P	Р	Þ	-	P	Р		BMDC	Note 2,3,4,5,7,8,10			
Small Organ (Note 1)		P	Р	Р	-	Р	Р		ВМОС	Note 2,3,4,5,7,8,10			
Neonatal Cephalic		Р	Р	₽		Р	Р		BMDC	Note 2,3,4,5,7,8,10			
Adult Cephalic										1.010 0201 1011 10110			
Cardiac													
Trans-esophageal													
Transrectal								······································					
Transvaginal													
Transurethral													
Intravascular									-	······································			
Peripheral vessel	~	Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10			
Laparoscopic										14010 2,0,4,0,1,0,10			
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10			
Musculo-skeletal Superficial		P	P	P		Р	Р		вмос	Note 2,3,4,5,7,8,10			
Other (specify)													

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 1	For	examp:	e:	breast	. testes.	thyroid.	penis.	prostate,	efc
	_						L 4	P. COLOROL	ow.

Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices 12063803

510 (k) Number (if known):

K063803

Device Name: Intended Use: VF13-5 Linear Array Transducer for use with ACUSON Antares
Ultrasound imaging or fluid flow analysis of the human body as follows:

	 									
						Me	ode of Opera	ation		
Clinical Application	А	В	M	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	I	Р	Р	P		Р	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal Intraoperative										
Neurological	<u></u>									
Pediatric		Р	P	Р		Р	₽		BMDC	Note 2,3,4,5,7,8,10
Small Organ (Note 1)		Р	P	P		Р	Р		BMDC	Note 2,3,4,5,7,8,10
Neonatal Cephalic		Р	Р	Р		Р	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac				<u> </u>						
Trans-esophageal			<u></u>]			
Transrectal		<u> </u>								
Transvaginal			L	l						
Transurethral										
Intravascular										
Peripheral vessel		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10
Musculo-skeletal Superficial		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 1	For example:	breast,	testes,	thyroid,	penis,	prostate, e	etc.
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Note 2 Ensemble tissue harmonic imaging

Note 3 SieClear multi-view spatial compounding

Note 4 Tissue Equalization Technology

Note 5 3-Scape real-time 3D imaging

Note 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number _

510 (k) Number (if known):

K063803

Device Name:

VFX13-5 Multi-D Array Transducer for use with ACUSON Antares

intended Ose:			Ultra	souna II	maging	or fluid flos	w analysis (of the huma	an body as	follows:
						Me	ode of Oper	ation		
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	O (Sp

1	<u></u>	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		Р	Р		BMDC	Note 2,3,4,5,7,8,10			
Abdominal		P	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10			
Intraoperative Abdominal													
Intraoperative Neurological													
Pediatric		P	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10			
Small Organ (Note 1)		P	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10			
Neonatal Cephalic		Ρ	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10			
Adult Cephalic													
Cardiac													
Trans-esophageal							· · ·						
Transrectal										·			
Transvaginal													
Transurethral									-				
Intravascular													
Peripheral vessel		P	Р	Р	i	Р	P		BMDC	Note 2,3,4,5,7,8,10			
Laparoscopic										11010 2/0/1/0/1/0/10			
Musculo-skeletal Conventional		P	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10			
Musculo-skeletal Superficial		Р	þ	P		Р	Р		BMDC	Note 2,3,4,5,7,8,10			
Other (specify)									- · - · - · - · - · - · - · - · - · - ·				

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 1	For example: breast,	testes, th	yroid, penis,	prostate, etc.
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Note 2 Ensemble tissue harmonic imaging

SieClear multi-view spatlal compounding Note 3

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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Sancy Chroden	Prescription Use (Per 21 CFR 801.109)
Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices KOG 38 02 510(k) Number	3

510 (k) Number (if known):

K063803

Device Name:

PX4-1 Phased Array Transducer for use with ACUSON Antares

Intended Use: 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	P	Р	P	Р		BMDC	Note 2,3,4,5,7,8,10			
Abdominal		Р	Р	P	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10			
Intraoperative Abdominal								-		11010 210, 110, 10			
Intraoperative Neurological													
Pediatric		Р	P	P	P	Р	Р		BMDC	Note 2,3,4,5,7,8,10			
Small Organ													
Neonatal Cephalic		P	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10			
Adult Cephalic		Р	Р	Р	Р	Р	P		BMDC	Note 2,3,4,5,7,8,10			
Cardiac		Р	Р	P	Р	P	Р		BMDC	Note 2,3,4,5,6,7,8,10			
Trans-esophageal			_							11010 210,1,010,110,10			
Transrectal								*****					
Transvaginal									· · · ·				
Transurethrai			-				 	·					
Intravascular													
Peripheral vessel		P	₽	P	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10			
Laparoscopic									211100	14000 2,0,1,0,10			
Musculo-skeletal Conventional					·			·					
Musculo-skeletal Superficial								<u>. </u>					
Other (specify)													

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

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 6 Cadence contrast agent imaging (cardiac only)

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 of Reproductive, Abdominal,

and Radiological Devices 510(k) Number

December 13, 2006

510 (k) Number (if known):

K063803

Device Name: Intended Use:

CH6-2 Curved Array Transducer for use with ACUSON Antares Ultrasound imaging or fluid flow analysis of the human body as follows:

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

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue narmonic im	aging
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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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Division Sign-Of

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number __

510 (k) Number (if known):

K063803

Device Name: Intended Use: CH4-1 Curved Array Transducer for use with ACUSON Antares
Ultrasound imaging or fluid flow analysis of the human body as follows:

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

N = new indication; P = previously cleared by FDA - K033196; E = added under Appendix E

Additional Comments:

Ν	ote	2	Ensemb	е	lissue	harmoni	С	imaging
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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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices 510(k) Number _____

510 (k) Number (if known):

K063803

Device Name: Intended Use: PH4-1 Phased Array Transducer for use with ACUSON Antares 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										
Fetal		P	P	Р		P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		Ρ	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8,10
Small Organ										
Neonatal Cephalic		P	Р	Р		Р	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic		P	Р	P		P	Р		BMDC	Note 2,3,4,5,7,8,10
Cardiac										
Trans-esophageal										
Transrectal		1								<u> </u>
Transvaginal								<u> </u>		
Transurethral										
Intravascular		1		T						
Peripheral vessel		Р	Р	P		P	Р		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic	1	1				ļ		l		
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Other (specify)

Note 2 E	nsemble	tissue	harmonic	imaging
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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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)()

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number ____

510 (k) Number (if known):

K063803

Device Name: Intended Use: P10-4 Phased Array Transducer for use with ACUSON Antares Ultrasound imaging or fluid flow analysis of the human body as follows:

						M	lode of Oper	ation		
Clinical Application	А	В	М	PWD	CMD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Ρ	Р	P	Р	. P	Р		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	Р	P	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological				<u> </u>				·	l :	
Pediatric		P	Р	P	P	P	Р		BMDC	Note 2,3,4,5,7,8,10
Small Organ										
Neonatal Cephalic		Р	Р	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic]						
Cardiac		P	Р	Р	P	Р	Р		BMDC	Note 2,3,4,5,6,7,8,10
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral			1							
Intravascular	L]						
Peripheral vessel		Р	P	P	Р	Р	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic				1						
Musculo-skeletal Conventional		Р	Ρ	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,10
Musculo-skeletal Superficial										
Other (specify)										

N = new Indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Ensemble tissue harmonic imaging Note 2

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 (cardiac only)

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)

(Division \$ign-Off Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number

510 (k) Number (if known):

K063803

Device Name: Indications For Use:

VF13-5SP Linear Array Transducer for use with ACUSON Antares Diagnostic Imaging or fluid flow analysis of the human body as follows:

						M	ode of Opera	ation		
Clinical Application	Α	В	M	PWD	CMD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Note 9)		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Neurological		Р	Р	Р		Ρ	Р		BMDC	Note 2,3,4,5,7,8,10
Pediatric		P	Ρ	P		Р	Р		BMDC	Note 2,3,4,5,7,8,10
Small Organ (Note 1)		Р	Р	Р		Р	Р	·	BMDC	Note 2,3,4,5,7,8,10
Neonatal Cephalic		P	Р	Р		P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac					İ					
Transesophageal										
Transrectal				<u> </u>]				<u> </u>	
Transvaginal										
Transurethral										
Intravascular		<u> </u>]			
Peripheral vessel		Р	P	P		Р	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional		P	P	Р		₽	Р		BMDC	Note 2,3,4,5,7,8,10
Musculo-skeletal Superficial		Р	Р	Р		Р	Р		вмос	Note 2,3,4,5,7,8,10
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 1	For example: breast,	testes thyroid	nenis	orostate	etc
1400	LOI EVOINDIE: DIEBOL	reares, myronu,	POINT.	prostate,	au.

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 9 For example: vascular, abdominal

Note 10 Clarify VE vascular enhancement technology

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription, Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number _____

510 (k) Number (if known): K063803

Device Name: Intended Use:

C5F1 Curved array mechanical 3D transducer for use with ACUSON Antares

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	Р	Р		P	Р		ВМОС	Note 2,3,4,5,7,8,10
Abdominal		Р	Р	Р		. P	Р		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		Р	P	P		Р	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ (Note 1)		Р	Р	P		Б	P		BMDC	Note 2,3,4,5,7,8,10
Neonatal Cephalic		Р	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac										
Trans-esophageal									 	
Transrectal										
Transvaginal										
Transurethral										
Intravascular									1	
Peripheral vessel		P	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		ВМОС	Note 2,3,4,5,7,8,10
Musculo-skeletal Superficial										
Other (specify)	<u> </u>									

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

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

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 7 B&W SieScape panoramic imaging

Note 8 Power SieScape panoramic imaging

Note 10 Clarify VE vascular enhancement technology

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Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number .

510 (k) Number (if known): K063803

Device Name: Intended Use: C7F2 Curved array mechanical 3D transducer for use with ACUSON Antares

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

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, e	Note 1	For example:	breast, test	es, thyroid,	penis,	prostate,	etc.
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Prescription Use (Per 21 CFR 801.109) Consum of Reproductive, Abdominal, and feedvological Devices Number ..

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

510 (k) Number (if known):

K063803

Device Name: Intended Use:

EV9F4 Curved Array Transducer for use with ACUSON Antares Ultrasound imaging or fluid flow analysis of the human body as follows:

						M	ode of Opera	ation		
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic			<u> </u>							
Fetai		Р	Ρ	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Abdominal										
Intraoperative Abdominal										· · · · · · · · · · · · · · · · · · ·
Intraoperative Neurological						· · ·				·
Pedlatric									 	
Small Organ (Note 1)		Ρ	Ρ	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic		Ρ	P	P		Р	P		ВМОС	Note 2,3,4,5,7,8
Adult Cephalic									[
Cardiac						· -				· · · · · · · · · · · · · · · · · · ·
Trans-esophageal									 	
Transrectal									† 	
Transvaginal		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8
Transurethral				-						
Intravascular					-			··	 +	
Peripheral vessel									 	
Laparoscopic									 	
Musculo-skeletal Conventional										· · · · · · · · · · · · · · · · · · ·
Musculo-skeletal Superficial						- , <u></u>				
Other (specify)						·			 	· · · · · · · · · · · · · · · · · · ·

N = new indication; P = previously cleared by FDA - K050034; E = added under Appendix E

Additional Comments:

No	te '	1	For example	e: breast,	testes,	thyroid,	penis,	prostate.	etc.
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Ensemble tissue harmonic imaging Note 2

Note 3 SieClear multi-view spatial compounding

Tissue Equalization Technology Note 4 Note 5

3-Scape real-time 3D imaging

B&W SieScape panoramic Imaging Note 7

Note 8 Power SieScape panoramic imaging

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> > Prescription Use (Per 21 CFR 801.109)

(Division Sign-Qff)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number_

510 (k) Number (if known):

K063803

Device Name: Intended Use: V5Ms Multiplane TEE Transducer for use with ACUSON Antares 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	T							······································		
Fetal				_						
Abdominal										· · · · · · · · · · · · · · · · · · ·
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ							1		<u> </u>	
Neonatal Cephalic							<u> </u>			
Adult Cephalic							· · - · · · · -			
Cardlac					-		 			
Trans-esophageal		Р.	P	Р	P	P	Р		BMDC	Note4
Transrectal	1 -								DIVIDO	11064
Transvaginal							- 			
Transurethral	1									
Intravascular							 			
Peripheral vessel							 		 	<u> </u>
Laparoscopic							 			
Musculo-skeletal Conventional										
Musculo-skeletal Superficial							<u> </u>			<u> </u>
Other (specify)										

N = new indication; P = previously cleared by FDA - K063138; E = added under Appendix E

Additional Comments:

Note 4 Tissue Equalization Technology

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number