APR 2 5 2008

ACUSON X300™ Ultrasound System

Special 510(k) Submission

## **SECTION 12**

#### 510(k) Summary

Sponsor:

Siemens Medical Solutions USA, Inc.,

Ultrasound Division 1230 Shorebird Way

Mountain View, California 94043

**Contact Person:** 

Martina Vogt

Telephone:

(425) 557 1434

Fax:

(425) 391 9198

**Submission Date:** 

March 14, 2008

Device Name:

ACUSON X300<sup>™</sup> ultrasound system SONOVISTA X300 ultrasound system

ACUSON X300<sup>™</sup> ultrasound system, premium edition

Common Name:

Diagnostic Ultrasound System with Accessories

Classification:

Regulatory Class:

H

Review Category: Classification Panel: Tier II Radiology

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

Product Code 90-IYN

Diagnostic Ultrasound Transducer

FR # 892.1560

Product Code 90-IYO

FR # 892.1570

Product Code 90-ITX

Diagnostic Intravascular Catheter

FR # 870.1200

Product Code 74-DQO

#### A. Legally Marketed Predicate Devices

The Siemens ACUSON X300 ultrasound system is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to our current product, the Siemens ACUSON X300 ultrasound system (K072676, K071036, K061946).

#### B. Device Description:

The Siemens ACUSON X300 has been designed to meet the following product safety standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
  - EN/IEC 60601-1
  - EN/IEC 60601-1-1
  - EN/IEC 60601-1-2
  - EN/IEC 60601-1-4

- EN/IEC 60601-1-6
- EN/IEC 60601-2-18
- EN/IEC 60601-2-25
- IEC 61157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

#### C. Intended Use

The Siemens ACUSON X300 ultrasound imaging system is intended for the following applications: General Radiology, Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Neonatal/Adult Cephalic, Cardiac, Transcsophageal, Pelvic, Transcranial, OB/GYN, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

#### D. Substantial Equivalence

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

#### E. Performance Data

The ACUSON X300 modifications are verified and validated according to the company's design control process.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Ms. Martina Vogt Regulatory Affairs Specialist Siemens Medical Solutions USA, Inc. Ultrasound Division 1230 Shorebird Way MOUNTAIN VIEW CA 94043

APR 2 5 2008

Re: K080760

Trade/Device Name: ACUSON X300 Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX, and DQO

Dated: March 14, 2008 Received: March 26, 2008

## Dear Ms. Vogt:

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 X300 Diagnostic Ultrasound System, as described in your premarket notification:

#### Transducer Model Number

C6-2 Convex Array
SoundStar 10F
P4-2 Phased Sector Array
CH5-2 Convex Array
VF10-5 Linear Array

L9-5 Linear Array
EC9-4 Convex Array Endocavity
EV9-4Convex Array
VF13-5 Linear Array
P8-4 Phased Array

BE9-4 Convex Array
CW2 Continuous Wave Doppler
CW5 Continuous Wave Doppler
AcuNav 8F Intracardiac
AcuNav 10F IntraCardiac
V5Ms TEE
4V1c Phased Array
VF13-5SP Linear Array
C8-5 Tightly Curved Array

8L3 Linear "Regel"
10V4 Phased Array Neonatal High
Frequency
C7F2 Curved Array
EV9F4 Curved Array Mechanical 3D/4D
L13F5 3D/4D Mechanical Wobbler Linear
VF8-3 Linear Array
P5-1 Phased Array

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" (21 CFR 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 <a href="http://www.fda.gov/cdrh/industry/support/index.html">http://www.fda.gov/cdrh/industry/support/index.html</a>

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

Sincerely yours,

Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

# **Indications for Use**

510(k) Number (if known):	
Device Name: ACUSON X300 Diagnostic Ultras	sound System
Indications For Use:	
The Siemens Acuson X300 ultrasound imaginal applications: General Radiology, Fetal, Abdor Neonatal/Adult Cephalic, Cardiac, Transesoph Urology, Vascular, Musculoskeletal, Superfict Vascular applications.  The system also provides for the measurement	minal, Intraoperative, Pediatric, Small Parts, hageal, Pelvic, Transcranial, OB/GYN, ial Musculoskeletal, and Peripheral
packages that provide information that is used	for clinical diagnosis purposes.
Prescription UseX AND/OR Part 21 CFR 801 Subpart D) PLEASE DO NOT WRITE BELOW THIS LINE-CON	Over-The-Counter Use (21 CFR 801 Subpart C)  NTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device	

(Division Sign Off) Division of Reproductive, Abdominal and

Radiological Devices
510(k) Number

510(k) Number (if known):

Device Name:

**ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

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

						Mo	ode of Opera	ation		· · · · · · · · · · · · · · · · · · ·
Clinical Application	A	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic									<del>                                     </del>	
Fetal		Р	Р	Р	Р	Ρ	Р		BMDC	Note 2,3,4,5,7,8,9
Abdominal		Р	Р	Р	P.	Р	Р	<del></del>		Note 2,3,4,5,7,8,9
Intraoperative (Note 6)		Р	P	Р	Р	Р	P		1	Note 2,3,4,5,7,8,9
Intraoperative Neurological		Р	P.	Р		P	Р		ВМДС	Note 2,3,4,5,7,8,9
Pediatric		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,9
Small Organ (Note 1)		Р	Р	Р	Р	Р	Р			Note 2,3,4,5,7,8,9
Neonatal Cephalic	!	Р	Р	Р	Р	P	Р		BMDC	Note 2,3,4,5,7,8,9
Adult Cephalic		Р	Р	Р	Р	Р	Р			Note 2,3,4,5,7,8,9
Cardiac		Р	Р	Р	Р	P	Р			Note 2,3,4,5,7,8,9
Transesophageal		Р	Р	Р	Р	Р	Р			Note 2,3,7,8,9
Transrectal		Р	Р	Р		Р	Р			Note 2,3,4,5,7,8,9
Transvaginal	لــــا	Р	Р	Р		Р	Р			Note 2,3,4,5,7,8,9
Transurethral										<u> </u>
Intravascular		Р	Р	Р	Р	P	P		BMDC	Note 2,3,7,8,9,10
Peripheral vessel		Р	Р	Р	Ρ	Р	P			Note 2,3,4,5,7,8,9
Laparoscopic										<u> </u>
Musculo-skeletal Conventional		Р	Р	P	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,9
Musculo-skeletal Superficial		P.	P	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,9
Other (specify)		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,7,8,9,10

N = new indication; P = previously cleared by K072676; E = added under Appendix E

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

Ensemble tissue harmonic imaging Note 2

3D imaging Note 3

B&W SieScape panoramic imaging Note 4

Note 5 Power SieScape panoramic imaging

For example: abdominal, vascular Note 6

Note 7 Contrast agent imaging

Note 8 SieClear multi-view spatial compounding

Note 9 Tissue Equalization Technology

Note 10 Intracardiac imaging

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Prescription Use (Per 21 CFR 801.109)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number -Seeti

Diagnostic Ultrasound Indications for Use Form

Pg. 6.3 of 6.29

510(k) Number (if known):

Device Name:

C6-2 Convex Array Transducer for use with:

**ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

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

			1			Mod	e of Operatio	n		
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N		N	N		вмос	Note 2,3,4,5,7,8,9
Abdominal		N	N	N		N	N		BMDC	Note
Intraoperative (Note 6)				ļ					<del> </del>	2,3,4,5,7,8,9
Intraoperative Neurological										
Pediatric		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8,9
Small Organ (Note 1)										2,0,4,0,1,0,3
Neonatal Cephalic					·					<del> </del> -
Adult Cephalic										<del> </del>
Cardiac		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8,9
Transesophageal										2,0,4,0,7,0,5
Transrectal										<u> </u>
Transvaginal							<del></del>			<del></del>
Transurethral								-	<del></del>	
Intravascular						<del></del>				<del> </del>
Peripheral vessel		N.	N	N		N	N		BMDC	Note 2,3,4,5,7,8,9
Laparoscopic		•							····	[ <u>~,0,4,0,7,0,8</u>
Musculo-skeletal (Conventional)		N	N	N		N	N		BMDC	Note
Musculo-skeletal (Superficial)			····							2,3,4,5,7,8,9
Other (specify)				<del>                                     </del>		<del></del>			· · · · · · · · · · · · · · · · · · ·	

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

ľ	lote	1 Foi	r example:	breast,	testes, t	hyroid,	penis.	prostate.	etc.

Note 10 Intracardiac imaging

long	(PLEASE DO NO	T WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off) Division of Reproductive	1	Prescription Use (Per 21 CFR 801.109)

Radiological Devices

510(k) Number

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

SieClear multi-view spatial compounding Note 8

Note 9 Tissue Equalization Technology

510(k) Number (if known):

Device Name:

SoundStar 10F Transducer for use with:

**ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

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

	Mode of Operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitud e Doppler	Color Velocity Imaging	Combine d (Specify)	Other (Specify)			
Ophthalmic										<del> </del>			
Fetal				1			<u> </u>		<del></del>	<del> </del>			
Abdominal							<del> </del>		<u> </u>	·			
Intraoperative (Note 6)							1		<del> </del>	<del> </del> -			
Intraoperative Neurological					· · · · · · ·	· · · · · · · · · · · · · · · · · · ·				ļ			
Pediatric									-	<del></del>			
Small Organ (Note 1)									<del>                                     </del>	<u> </u>			
Neonatal Cephalic			-				·			<del></del>			
Adult Cephalic							·		-	<del> </del>			
Cardiac		N	N	N	N	N	N		BMDC	Note 2,3,7,8,9,10			
Transesophageal								<u>-</u>		2,0,1,0,9,10			
Transrectal									<del> </del>	<del></del>			
Transvaginal										ļ			
Transurethral							<del> </del>	<del></del>	-				
Intravascular		N	N	N	N	N	N		BMDC	Note 2,3,7,8,9,10			
Peripheral vessel										12,0,1,0,0,10			
Laparoscopic													
Musculo-skeletal (Conventional)													
Musculo-skeletal (Superficial)						·							
Other (intra-cardiac)		N	N	N	N	N	N		BMDC	Note 2,3,7,8,9,10			

new indication; P = previously cleared by FDA; E = added under Appendix E.

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

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Prescription Use (Per 21 CFR 801.109)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

2080 760

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

B&W SieScape panoramic imaging Note 4

Power SieScape panoramic imaging Note 5

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

SieClear multi-view spatial compounding Note 8

Tissue Equalization Technology Note 9

Note 10 Intracardiac imaging

510(k) Number (if known):

Device Name:

P4-2 Phased Sector Array Transducer for use with:

**ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

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

						Mo	de of Opera	tion		
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic		ļ								l
Fetal		Р	P	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,9
Abdominal		Р	Р	Р	P	Р	Р			Note 2,3,5,6,7,8,9
Intraoperative (Note 6)							·		- Jimbo	140.6 2,3,3,0,7,0,9
Intraoperative Neurological										
Pediatric		Р	Р	Р	Р	Р	P		BMDC	Note 2,3,4,5,7,8,9
Small Organ (Note 1)						<del></del> ,			DINIDO	140te 2,0,4,0,7,0,9
Neonatal Cephalic		Ω.	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,9
Adult Cephalic		P	P	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,9
Cardiac		P	Р	Р	Р	Р	Р			Note 2,3,4,5,7,8,9
Transesophageal										14010 2,0,4,0,1,0,3
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		Р	P	P	Р	Р	P		BMDC	Note 2,3,4,5,7,8,9
Laparoscopic									200	100 2,0,4,3,7,0,8
Musculo-skeletal Conventional										
Musculo-skeletal Superficial						<del></del>				
Other (specify)										

N = new indication; P = previously cleared by K072676; E = added under Appendix E

Note 1	For example: breast.	toetoe	thursial			_4_
MOTOL	FOI EXAMBLE: Dreast.	testes.	invroia.	DANIS	orostate	atc

Note 10 Intracardiac imaging

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(Division Sign-Off)

Prescription Use (Per 21 CFR 801.109)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number Section

Diagnostic Ultrasound Indications for Use Form

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Ensemble tissue harmonic imaging Note 2

<sup>3</sup>D imaging Note 3

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

For example: abdominal, vascular Note 6

Note 7 Contrast agent imaging

SieClear multi-view spatial compounding Note 8

Tissue Equalization Technology

510(k) Number (if known):

Device Name:

CH5-2 Convex Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

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

			<u> </u>			М	ode of Opera	ation		
Abdominal Intraoperative (Note 6) Intraoperative Neurological Pediatric Small Organ (Note 1) Neonatal Cephalic Adult Cephalic Cardiac Transesophageal Transrectal Transvaginal Transurethral Intravascular Peripheral vessel Laparoscopic	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic									<del> </del>	
Fetal		Р	Р	Р		Р	P		BMDC	Note 2,3,4,5,7,8,9
Abdominal		Р	Р	Р		P	P		BMDC	
(Note 6)							·		DIVIDO	Note 2,3,4,5,7,8,9
Neurological										
Pediatric		P	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Small Organ (Note 1)									DIVIDO	14016 2,5,4,5,7,8,9
Neonatal Cephalic										
Adult Cephalic									· · · · · · · · · · · · · · · · · · ·	
Cardiac		Р	Р	P		Р	Р		BMDC	Note 2 2 4 5 7 0 0
Transesophageal							<del>  </del>		DIVIDO	Note 2,3,4,5,7,8,9
Transrectal										· · · · · · · · · · · · · · · · · · ·
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		Р	Р	Р		Р	Р	-	BMDC	Note 2 2 4 5 7 0 0
Laparoscopic						<del></del>	<u>-</u>	<u> </u>	DIVIDO	Note 2,3,4,5,7,8,9
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		BMDC	Note 2.3.4.5.7.8.9
Musculo-skeletal Superficial										
Other (specify)							<del></del>			<del></del>

N = new indication; P = previously cleared by K072676; E = added under Appendix E

Note 1	For exa	mple:	breast,	testes,	thyroid.	penis.	prostate.	etc
51 - C							,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	

Note 10 Intracardiac imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Prescription Use (Per 21 CFR 801.109)

Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number \_\_\_\_

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Diagnostic Ultrasound Indications for Use Form

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Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 SieClear multi-view spatial compounding

Note 9 Tissue Equalization Technology

510(k) Number (if known):

Device Name:

VF10-5 Linear Array Transducer for use with:

**ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

Diagnostic 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 "						magnig	<del> </del>	
Fetal		P	Р	Р		Р	Р		BMDC	Note 0.045700
Abdominal		Р	Р	Р		P	P		BMDC	Note 2,3,4,5,7,8,9
Intraoperative (Note 6)								<del>-</del>	DIVIDO	Note 2,3,4,5,7,8,9
Intraoperative Neurological					_					
Pediatric		P	Ρ	Р		Р	Р	<del></del>	BMDC	Note 2,3,4,5,7,8,9
Small Organ (Note 1)		Ρ	Ρ	Р		Р	P			Note 2,3,4,5,7,8,9
Neonatal Cephalic		Р	Р	Р		Р	Р		·	Note 2,3,4,5,7,8,9
Adult Cephalic								<del></del>	BIVIDO	14018 2,0,4,0,7,0,9
Cardiac								<del></del>		<del>.</del>
Transesophagea!						·				
Transrectal										· · · · · · · · · · · · · · · · · · ·
Transvaginal						•	<del></del>		,	
Transurethral							<del></del>			
Intravascular					<del></del>					
Peripheral vessel		Р	P	Р		P	Р		BMDC	Nete On 45700
Laparoscopic							·-·-		DIVIDO	Note 2,3,4,5,7,8,9
Musculo-skeletal Conventional		Ė	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Musculo-skeletal Superficial		Р	Р	Р		Р	Р			Note 2,3,4,5,7,8,9
Other (specify)						*				, , , , , , , , , , , , ,

N = new indication; P = previously cleared by K072676; E = added under Appendix E

Note t	For example: breast, testes, thyroid, penis, prostate, etc.
10101	TO Example, preast, testes, thyroto, penis, prostate etc.
Nieke A	English to the state of the sta

Ensemble tissue harmonic imaging Note 2

Note 3 3D imaging

Note 4

B&W SieScape panoramic imaging Power SieScape panoramic imaging Note 5

Note 6 For example: abdominal, vascular

Contrast agent imaging Note 7

Note 8 SieClear multi-view spatial compounding

Tissue Equalization Technology Note 9

Note 10 Intracardiac imaging

Norm no	(PLEASE DO NOT V	WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) oncurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)	0	
Division of Reproductive	, Abdominal and	Prescription Use (Per 21 CFR 801.109)
Radiological Devices 510(k) Number	K080760_	· · · · · · · · · · · · · · · · · · ·

510(k) Number (if known):

Device Name:

L9-5 Linear Array Transducer for use with:

**ACUSON X300 Diagnostic Ultrasound Systems** 

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	Р	P		Р	Р		BMDC	Note 2.3.4.5.7.8.9
Abdominal		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		Ρ	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Small Organ (Note 1)		Р	Р	Р		Р	Р			Note 2,3,4,5,7,8,9
Neonatal Cephalic		Р	Ρ	P		. Р	Р		BMDC	Note 2,34,5,7,8,9
Adult Cephalic										
Cardiac								***		
Transesophageal		<u> </u>								
Transrectal										
Transvaginal										
Transurethral										· · · · · · · · · · · · · · · · · · ·
Intravascular										
Peripheral vessel		Ρ	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Laparoscopic										-,-, ,-,-,-
Musculo-skeletal Conventional		Р	Ρ	Þ		Р	P		BMDC	Note 2,3,4,5,7,8,9
Musculo-skeletal Superficial		æ	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Other (specify)									-	<del></del> -

N = new indication; P = previously cleared by K072676; E = added under Appendix E

Note	1	-or	examp	le:	breast	i, 1	testes,	, thy	roid,	penis,	prostate	, etc
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Note 10 Intracardiac imaging

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(Division Sign-Off)

Prescription Use (Per 21 CFR 801.109)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

Diagnostic Ultrasound Indications for Use Form

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Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

B&W SieScape panoramic imaging Note 4

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 SieClear multi-view spatial compounding

**Tissue Equalization Technology** Note 9

510(k) Number (if known):

Device Name:

EC9-4 Convex Array Endocavity Transducer for use with:

**ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

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

			-			M	ode of Opera	ation		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic								<u></u>		
Fetal		Р	Р	P		Р	· P		BMDC	Note 2,3,4,5,7,8,9
Abdominal									5,4,50	11015 2,0,4,0,7,0,5
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric						-		<del></del>		<u> </u>
Small Organ (Note 1)		Р	Р	Р		Р	Р		ВМДС	Note 2,3,4,5,7,8,9
Neonatal Cephalic		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Adult Cephalic										1010 = 101 11011 1010
Cardiac			L							
Transesophageal										
Transrectal		Р	Р	Р		P	Ρ		BMDC	Note 2,3,4,5,7,8,9
Transvaginal		Р	Ρ	P		Р	Р			Note 2,3,4,5,7,8,9
Transurethral								.=.*		
Intravascular										
Peripheral vessel								·-···		
Laparoscopic										
Musculo-skeletal Conventional		,								
Musculo-skeletal Superficial										
Other (specify)								<del></del>		

N = new indication; P = previously cleared by K072676; E = added under Appendix E

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

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 SieClear multi-view spatial compounding

Note 9 Tissue Equalization Technology

Note 10 Intracardiac imaging

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(Division Sign-Off) Division of Reproductive, Abdominal and	Prescription Use (Per 21 CFR 801.109)
Radiological Devices	

Section 6

510(k) Number

510(k) Number (if known):

**Device Name:** 

EV9-4 Convex Array Transducer for use with:

ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

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

						M	lode of Oper	ation		
Clinical Application	Α	В	М	PWD	CMD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic		ĺ.,								
Fetal		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Abdominal										
Intraoperative (Note 6)										···
Intraoperative Neurological			_						_	
Pediatric				T					f ·	
Small Organ (Note 1)		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Neonatal Cephalic		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Adult Cephalic										1.
Cardiac										
Transesophageal										
Transrectal		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Transvaginal		P	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Transurethral									· · · · · ·	, , , , , , , , , , , , , , , , , , , ,
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletai Conventional										· · · · · · · · · · · · · · · · · · ·
Musculo-skeletal Superficial										
Other (specify)	<u> </u>		i	†			<u> </u>			·

N = new indication; P = previously cleared by K072676; E = added under Appendix E

Note 1	For example: breast, testes, thyroid, penis, prostate, etc.
Note 2	Ensemble tissue harmonic imaging
Note 3	3D imaging
Note 4	B&W SieScape panoramic imaging
Note 5	Power SieScape panoramic imaging
Note 6	For example: abdominal, vascular
Note 7	Contrast agent imaging
Note 8	SieClear multi-view spatial compounding

Note 9 Tissue Equalization Technology

Section 6

Note 10 Intracardiac imaging	
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(Division Stgn-Off)	oncurrence of CDRH, Office of Device Evaluation (ODE)
Division of Reproductive, Abdominal and	Prescription Use (Per 21 CFR 801.109)
Radiological Devices 510(k) Number 1608 360	

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

VF13-5 Linear Array Transducer for use with:

ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

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

						М	ode of Oper	ation		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		Р	Р		BMDC	Note 2.3.4.5.7.8.9
Abdominal		Р	P	Р		Р	Р	-	BMDC	Note 2,3,4,5,7,8,9
Intraoperative (Note 6)		•								
Intraoperative Neurological								-		
Pediatric		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Small Organ (Note 1)		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Neonatal Cephalic		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8,9
Adult Cephalic										
Cardiac								<del></del>		<u> </u>
Transesophageal										
Transrectal										-
Transvaginal				I						
Transurethral										
Intravascular										
Peripheral vessel		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Laparoscopic										
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Musculo-skeletal Superficial		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Other (specify)	1						,	-		

N = new indication; P = previously cleared by K072676; E = added under Appendix E

Note 1	For example: bre	east, testes, th	lyroid, penis,	, prostate, etc.
				-

Note 2 Ensemble tissue harmonic imaging

Note 3

3D imaging B&W SieScape panoramic imaging Note 4

Power SieScape panoramic imaging Note 5

Note 6 For example: abdominal, vascular

Contrast agent imaging Note 7

Note 8 SieClear multi-view spatial compounding Note 9 Tissue Equalization Technology

Note 10 Intracardiac imaging

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510(k) Number <u>K080 760</u>		
Section 6	Diagnostic Ultrasound Indications for Use Form	Pg. 6.10 of 6.29

510(k) Number (if known):

Device Name:

P8-4 Phased Array Transducer for use with:

**ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

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

				_		M	ode of Oper	ation		
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	Р	P	Р	Р	P		BMDC	Note 2,3,4,5,7,8,9
Abdominal		P	Р	P	þ	Р	Р		BMDC	Note 2,3,45,7,8,9
Intraoperative (Note 6)										
Intraoperative Neurological									1	
Pediatric		P	Р	Р	P	Р	Р		BMDC	Note 2,3,4,5,7,8,9
Small Organ (Note 1)										,
Neonatal Cephalic	l	P	Р	Р	P	P	Р		BMDC	Note 2,3,4,5,7,8,9
Adult Cephalic	-			T						
Cardiac		Р	Р	Р	Р	P	Р		BMDC	Note 2,3,4,5,7,8,9
Transesophageal										
Transrectal										
Transvaginal				i					i	
Transurethral										
Intravascular										
Peripheral vessel		Р	Р	P	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,9
Laparoscopic										1 · · · · · · · · · · · · · · · · · · ·
Musculo-skeletal Conventional		Р	Р	Р	P	Р	P		BMDC	Note 2,3,4,5,7,8,9
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by K072676; E = added under Appendix E

Note 1	For example: breas	t, testes, thyroid,	penis, prostate, etc.
	- 11 1		

Note 2 Ensemble tissue harmonic imaging

3D imaging Note 3

B&W SieScape panoramic imaging Note 4 Note 5

Power SieScape panoramic imaging For example: abdominal, vascular Note 6

Contrast agent imaging Note 7

Note 8 SieClear multi-view spatial compounding

Tissue Equalization Technology Note 9

Note 10 Intracardiac imaging	
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(Division Sign-Off) Prescription Use (Per 2	1 CFR 801.109)
Division of Reproductive, Abdominal and	
Radiological Devices	
510(k) Number 1080960	

Section 6

510(k) Number (if known):

Device Name:

BE9-4 Convex Array Transducer for use with:

**ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

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

	ļ					M	ode of Oper	ation	- "	
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		BMDC	Note 2,3,4,5,7,8,9
Abdominal										1010 210 11011 1010
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric									<del> </del>	<del></del> -
Small Organ (Note 1)		Р	Р	P,		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Neonatal Cephalic		Р	P	P		P	Р		BMDC	Note 2,3,4,5,7,8,9
Adult Cephalic										
Cardiac										
Transesophageal									<u> </u>	
Transrectal		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Transvaginal		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Transurethral										
intravascular										
Peripheral vessel										
Laparoscopic								· · · · · · ·		
Musculo-skeletal Conventional								<del></del>		
Musculo-skeletal Superficial										
Other (specify)							· · ·			<del></del>

N = new indication; P = previously cleared by K072676; E = added under Appendix E

Note 1	For	example:	breast.	testes	thyroid	nanie	prostate	atc
		OALLINDIO.	Digasi,	legies,	u ivi olu.	Deriio.	DIUSIALE.	eic.

Note 10 Intracardiac imaging

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Radiological Devices

510(k) Number

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Power SieScape panoramic imaging Note 5

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 SieClear multi-view spatial compounding

Note 9 Tissue Equalization Technology

510(k) Number (if known):

Device Name:

CW2 Continuous Wave Doppler Transducer for use with:

**ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

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

	L					M	ode of Opera	ation		
Clinical Application	А	В	М	PWD	CMD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	"									
Fetal					Р				1	
Abdominal					P	·····	1			
Intraoperative (Note 6)					Р					
Intraoperative Neurological						<u> </u>		·		
Pediatric					P					
Small Organ (Note 1)					Р					
Neonatal Cephalic	Π				Р					
Adult Cephalic				1	Р			-		
Cardiac					Р				<del>  </del>	
Transesophageal	T								<u> </u>	
Transrectal										
Transvaginal										<del></del>
Transurethral							1		<del>                                     </del>	
Intravascular				Γ			1			
Peripheral vessel	<u> </u>				Р				T	
Laparoscopic									<del>                                     </del>	
Musculo-skeletal Conventional					Р					
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by K072676; E = added under Appendix E

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

Ensemble tissue harmonic imaging

Note 10	• • • • • • • • • • • • • • • • • • • •
Note 9	Tissue Equalization Technology
Note 8	SieClear multi-view spatial compounding
Note 7	Contrast agent imaging
Note 6	For example: abdominal, vascular
Note 5	Power SieScape panoramic imaging
Note 4	B&W SieScape panoramic imaging
Note 3	3D imaging

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Division of Reproductiv Radiological Devices	e, Abdominal and	
510(k) Number	K080760	

Note 1

510(k) Number (if known):

Device Name:

CW5 Continuous Wave Doppler Transducer for use with:

**ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

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

	<u></u>					M	ode of Opera	ation		
Clinical Application	А	В	М	PWD	CMD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal			-		Р			<del></del>	<del>                                     </del>	
Abdominal					Р			·	<del></del>	· · · · · · · · · · · · · · · · · · ·
Intraoperative (Note 6)					Р					
Intraoperative Neurological			. "					<u>w</u> :		
Pediatric					Р		<del>                                     </del>		<del> </del>	
Small Organ (Note 1)					Р					
Neonatal Cephalic					Р					
Adult Cephalic					Р				<del>-</del>	
Cardiac					Р	<del></del>			· · · · · · · · · · · · · · · · · · ·	
Transesophageal										
Transrectal							<del></del>			
Transvaginal									<del></del>	
Transurethral										
Intravascular										
Peripheral vessel					Р			<del></del> .		
Laparoscopic										<del></del>
Musculo-skeletal Conventional					Р					
Musculo-skeletal Superficial										
Other (specify)								<del></del> -		

Note 5 Power SieScape panoramic imaging Note 6 For example: abdominal, vascular Note 7 Contrast agent imaging SleClear multi-view spatial compounding Note 8 Note 9 Tissue Equalization Technology Note 10 Intracardiac imaging (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** 

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

Ensemble tissue harmonic imaging

B&W SieScape panoramic imaging

Section 6

510(k) Number

Note 1

Note 2

Note 3

Note 4

3D imaging

510(k) Number (if known):

Device Name:

AcuNav 8F Intracardiac Transducer for use with:

**ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

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												
Abdominal												
Intraoperative (Note 6)												
Intraoperative Neurological												
Pediatric	T	Р	Р	Р	P	Р	Р		BMDC	Note 2,3,7,8,9,10		
Small Organ (Note 1)												
Neonatal Cephalic												
Adult Cephalic												
Cardlac		Р	Р	Р	P	P	Р		BMDC	Note 2,3,7,8,9,10		
Transesophageal												
Transrectal												
Transvaginal												
Transurethral					j							
Intravascular		P	P	Р	Р	Р	Р		BMDC	Note 2,3,7,8,9,10		
Peripheral vessel												
Laparoscopic												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial										,		
Other (Intra-cardiac)	<u> </u>	Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,7,8,9,10		

N = new indication; P = previously cleared by K072676; E = added under Appendix E

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

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 SieClear multi-view spatial compounding

Note 9 Tissue Equalization Technology

Note 10 Intracardiac imaging

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(Division Sign-Off) Division of Reproductive, Abdominal and	Prescription Use (Per 21 CFR 801.109)

Radiological Devices

510(k) Number \_\_\_\_\_

510(k) Number (if known):

Device Name:

AcuNav 10F Intracardiac Transducer for use with:

**ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

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

						М	ode of Oper	ation		
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										[
Fetal										
Abdominal										
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,7,8,9,10
Small Organ (Note 1)										
Neonatal Cephalic	1						Ĭ <u></u>			
Adult Cephalic				l					Ī	
Cardiac		Р	Р	P	Р	Р	P		BMDC	Note 2,3,7,8,9, 10
Transesophageal										
Transrectal				L				·		
Transvaginal	<u> </u>			I	l					
Transurethral					<u> </u>					
Intravascular		P	Р	Р	P	Р	P		BMDC	Note 2,3,7,8,9,10
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial			-							
Other (Intra-cardiac)		Р	Р	Р	Р	P	Р		BMDC	Note 2,3,7,8,9,10

N = new indication; P = previously cleared by K072676; E = added under Appendix E

Note 1 F	For example: brea	st, testes, thyroid,	, penis, prostate, etc.
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Note 10 Intracardiac imaging

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Prescription Use (Per 21 CFR 801.109)

Division of Reproductive, Abdominal and

Radiological Devices

(Division Sign-Off)

510(k) Number

K080760

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 SieClear multi-view spatial compounding

Note 9 Tissue Equalization Technology

510(k) Number (if known):

Device Name:

V5Ms TEE Transducer for use with:

**ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

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

· · · · · · · · · · · · · · · · · · ·						М	ode of Oper	ation		
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Note 6)										
Intraoperative Neurological				<u> </u>						
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		Р	Р	P	Р	Р	Р		BMDC	Note 2,3,7,8,9
Transesophageal		P	P	Р	Р	P	Р		BMDC	Note 2,3,7,8,9
Transrectal	<u> </u>									
Transvaginal										
Transurethral			Ŀ							
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)			T						1	

N = new indication; P = previously cleared by K072676; E = added under Appendix E

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

Note 3 3D imaging

Note 4 **B&W SieScape** panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 SieClear multi-view spatial compounding

Tissue Equalization Technology Note 9

Note 10 Intracardiac imaging

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Division Sign-Off)	on Use (Per 21 CFR 801.109)
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Radiological Devices

510(k) Number

510(k) Number (if known):

Device Name:

4V1c Phased Array Transducer for use with:

**ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

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

out to the second	ļ		,			M	lode of Oper	ation		
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	<u> </u>							gg		
Fetal		P	Ρ	Р	Р	Р	Р		BMDC	Note 2 2 4 5 7 0 0
Abdominal		Р	Р	Р	Р	Р	P			Note 2,3,4,5,7,8,9
Intraoperative (Note 6)								<u> </u>	DIVIDO	Note 2,3,5,6,7,8,9
Intraoperative Neurological										
Pediatric		Р	Р	Р	P	Р	P		BMDC	N-1-004===
Small Organ (Note 1)							•		BMDC	Note 2,3,4,5,7,8,9
Neonatal Cephalic		Р	Р	Р	Р	Р	P		BMDC	Mata 0.0 4 7 7 7 7
Adult Cephalic		P	Ρ	Р	Р	P	P			Note 2,3,4,5,7,8,9
Cardiac		Р	Р	Р	P	P	P			Note 2,3,4,5,7,8,9
Transesophageal							<u></u>		BMDC	Note 2,3,4,5,7,8,9
Transrectal										· · · · · · · · · · · · · · · · · · ·
Transvaginal					<del></del>					
Transurethral										
Intravascular					<del></del>					
Peripheral vessel		P	Р	Р	Р	P	Р	<del></del>	DUDD	
Laparoscopic				<del></del>	<del></del>				BMDC	Note 2,3,4,5,7,8,9
Musculo-skeletal Conventional										
Musculo-skeletal Superficial						·				
Other (specify)							<del></del>			

Note 5 Power SieScape panoramic imaging For example: abdominal, vascular Note 6 Note 7 Contrast agent imaging Note 8 SieClear multi-view spatial compounding Note 9 Tissue Equalization Technology Note 10 Intracardiac imaging 24PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) (Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE) Division of Reproductive, Abdominal and Prescription Use (Per 21 CFR 801.109) Radiological Devices 510(k) Number

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

Ensemble tissue harmonic imaging

B&W SieScape panoramic imaging

3D imaging

Note 1 Note 2

Note 3

Note 4

510(k) Number (if known):

Device Name:

VF13-5SP Linear Array Transducer for use with: ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

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

						М	ode of Oper	ation		
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										-
Fetal			L							
Abdominal			L	·					***	
Intraoperative (Note 6)		P	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8,9
Intraoperative Neurological		Р	Р	Р		Р	P		BMDC	Note 2,3,4,5,7,8,9
Pediatric		Р	Р	Р		Ρ	Р		BMDC	Note 2,3,4,5,7,8,9
Small Organ (Note 1)		Р	Р	Р		Р	Р			Note 2,3,4,5,7,8,9
Neonatal Cephalic		P	Р	Р	<u> </u>	Р	Р		BMDC	Note 2,3,4,5,7,8,9
Adult Cephalic										, , , , , ,
Cardiac										
Transesophageal									· · · · · ·	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	Р	P.		2	P		BMDC	Note 2,3,4,5,7,8,9
Laparoscopic										B. B
Musculo-skeletal Conventional		P	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Musculo-skeletal Superficial		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8,9
Other (specify)		I			<b></b>					<u> </u>

N = new indication; P = previously cleared by K072676; E = added under Appendix E

Note 1	For example: breast, testes, thyroid, penis, prostate, etc.
Note 2	Ensemble tissue harmonic imaging
Note 3	3D imaging
Note 4	B&W SieScape panoramic imaging
Note 5	Power SieScape panoramic imaging
Note 6	For example: abdominal, vascular
Note 7	Contrast agent imaging

Note 8 SieClear multi-view spatial compounding
Note 9 Tissue Equalization Technology
Note 10 Intracardiac imaging

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Division of Reproductive, A Radiological Devices	Prescription Use (Per 21 CFR 801.109)
510(k) Number	080760
Section 6	Diagnostic Ultrasound Indications for Use Form Pg 6.19 of 6.29

510(k) Number (if known):

Device Name:

C8-5 Tightly Curved Array Transducer for use with: **ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

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

						М	ode of Oper	ation		
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic				i				<u></u>		
Fetal		Р	Ք	P	1	Р	Р	<del></del>	BMDC	Note 2,3,4,5,7,8,9
Abdominal		Р	Ρ	Ρ.		Р	Р			Note 2,3,5,6,7,8,9
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Small Organ (Note 1)		Р	Р	Р		Р	Р			Note 2,3,4,5,7,8,9
Neonatal Cephalic		P	Ρ	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Adult Cephalic		Р	Ρ	Р		Р	Р			Note 2,3,4,5,7,8,9
Cardiac		P	Р	Р		Р	Р		,	Note 2,3,4,5,7,8,9
Transesophageal										
Transrectal	<u>.                                    </u>									
Transvaginal										
Transurethral										
Intravascular									·	· ·
Peripheral vessel		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Laparoscopic								···		
Musculo-skeletal Conventional		Р	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Musculo-skeletal Superficial		Р	Р	P		Р	P		BMDC	Note 2,3,4,5,7,8,9
Other (specify)		<u> </u>							l	

N = new indication; P = previously cleared by K072676; E = added under Appendix E

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

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Power SieScape panoramic imaging Note 5

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 SieClear multi-view spatial compounding

Tissue Equalization Technology Note 9

Note 10 Intracardiac imaging

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Prescription Use (Per 21 CFR 801,109)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number - Section

Diagnostic Ultrasound Indications for Use Form

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510(k) Number (if known):

Device Name:

8L3 Linear "Regel" Transducer for use with:

**ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

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

					:	М	ode of Oper	ation		
Clinical Application	А	В	М	PWD	CWD	Colar Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic				İ						
Fetal		Р	ρ.	P		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Abdominal		P	Р	P		P	Р			Note 2,3,4,5,7,8,9
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		Р	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Small Organ (Note 1)		P	Р	Р		Р	Р			Note 2,3,4,5,7,8,9
Neonatal Cephalic		P	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8,9
Adult Cephalic										-,-,-,-,-,-,-,-,-,-,-,-,-,-,-,-,-,-,-,
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										·
Transurethral										
Intravascular										
Peripheral vessel		Р	P	Р		P	Р		BMDC	Note 2,3,4,5,7,8,9
Laparoscopic	1						· · · · · · · · · · · · · · · · · · ·			
Musculo-skeletal Conventional		Р	P	Р		P	Р		BMDC	Note 2,3,4,5,7,8,9
Musculo-skeletal Superficial		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8,9
Other (specify)				<u> </u>						

N = new Indication; P = previously cleared by K072676; E = added under Appendix E

Note 1	For example: breast, testes, thyroid, penis, prostate, etc.
Note 2	Ensemble tissue harmonic imaging
Note 3	3D imaging
Note 4	B&W SieScape panoramic imaging
Note 5	Power SieScape panoramic imaging

Note 5
Power SieScape panoramic imaging
Note 6
For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 SieClear multi-view spatial compounding

Note 9 Tissue Equalization Technology

Note 10 Intracardiac imaging

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510(k) Number (if known):

Device Name:

10V4 Phased Array Neonatal High Frequency Transducer for use with:

**ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

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

						М	ode of Opera	ation		
Clinical Application	Α	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	P	Р	Р	Ρ	Р		BMDC	Note 2,3,4,5,7,8,9
Abdominal		Р	P	Р	Р	Р	Р			Note 2,3,45,7,8,9
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		Р	Р	Р	Р	Р	Р	-	BMDC	Note 2,3,4,5,7,8,9
Small Organ (Note 1)										
Neonatal Cephalic		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,9
Adult Cephalic				1						. , , , , , , , , , , , , , , , , , , ,
Cardiac		Р	Р	Р	P	Р	Р		BMDC	Note 2,3,4,5,7,8,9
Transesophageal		·								, , , , , , , , , , , , , , , , , , , ,
Transrectal										
Transvaginal										
Transurethral						<del></del>				
Intravascular									1	
Peripheral vessel		Р	Р	Р	P	. Р	Р		BMDC	Note 2,3,4,5,7,8,9
Laparoscopic						<del></del>				111111111111
Musculo-skeletal Conventional		Р	Р	Р	P	Р	Р		BMDC	Note 2,3,4,5,7,8,9
Muscuio-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by K072676; E = added under Appendix E

Note 1	For example:	hreast	testes t	hyroid	nenie	proetete	ato
14010 1	I OI GABIIIDIG.	DIGGSL,	lesies, t	HYLOIG,	Perilo.	PIUSIAIB.	wit.

Note 10 Intracardiac imaging

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Division of Reproductive, Abdominal and

Prescription Use (Per 21 CFR 801.109)

Radiological Devices

510(k) Number 8080760

Diagnostic Ultrasound Indications for Use Form

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 SieClear multi-view spatial compounding

Note 9 Tissue Equalization Technology

510(k) Number (if known):

Device Name:

C7F2 Curved Array Mechanical 3D/4D Transducer for use with:

**ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

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

	<u> </u>					M	ode of Oper	ation		
Clinical Application	A	В	М	PWD	ÇWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										·
Fetal		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Abdominal		P	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8,9
Intraoperative (Note 6)						<del></del>				11000 2,0,4,0,7,0,3
Intraoperative Neurological										
Pediatric		Р	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Small Organ (Note 1)									555	11010 2,0,7,0,5
Neonatal Cephalic										
Adult Cephalic		_								- · · · · · · · · · · · · · · · · · · ·
Cardiac		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5,7,8,9
Transesophageal									B.11.00	11010 2,0,4,0,7,0,8
Transrectal										
Transvaginal									<del></del>	
Transurethral							<del></del>			
Intravascular								·		
Peripheral vessel		P	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Laparoscopic				_						. 10.0 2,0,7,0,7,0,0
Musculo-skeletal Conventional		P	P	Р		Р	Р		BMDC	Note 2.3.4.5.7.8.9
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by K072676; E = added under Appendix E

Note 1	For example: breast,	testes, thyroid	nenis	prostate d	ate

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 SieClear multi-view spatial compounding

Note 9 Tissue Equalization Technology

Note 10 Intracardiac imaging

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Division of Reproductive, Abdominal and

Prescription Use (Per 21 CFR 801.109)

Radiological Devices

510(k) Number Section 6

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

EV9F4 Curved Array Mechanical 3D/4D Transducer for use with:

**ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

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

						М	ode of Oper	ation		
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Ъ	Р		Р	P		BMDC	Note 2,3,4,5,7,8,9
Abdominal										100 2011,017,010
Intraoperative (Note 6)								· •		
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		Р	Р	Р		P <sub>.</sub>	Р	<del></del>	BMDC	Note 2,3,4,5,7,8,9
Neonatal Cephalic		P	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Adult Cephalic										-,-,-,-,-,-,-,-
Cardiac										
Transesophageal										
Transrectal		P	Ω	Р		P	P		BMDC	Note 2,3,4,5,7,8,9
Transvaginal		Р	Ρ	Р		Р	P			Note 2,3,4,5,7,8,9
Transurethral					<u> </u>					,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Intravascular										
Peripheral vessel										
Laparoscopic				l						
Musculo-skeletal Conventional										
Musculo-skeletal Superficial						<del></del>		•		
Other (specify)				1			<b>—</b>			

N = new indication; P = previously cleared by K072676; E = added under Appendix E

Note	rar	example:	breast,	testes,	thyroid,	penis,	prostate	a. etc.
	_					• •		

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 SieClear multi-view spatial compounding

Note 9 Tissue Equalization Technology

Note 10 Intracardiac imaging

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Division of Reproductive, Abdominal and

Prescription Use (Per 21 CFR 801.109)

Radiological Devices

510(k) Number

Diagnostic Ultrasound Indications for Use Form

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510(k) Number (if known):

Device Name:

L13F5 3D/4D Mechanical Wobbler Linear Transducer for use with:

**ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

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

						М	ode of Oper	ation	-	
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Δ.	Р		P	Р		BMDC	Note 2,3,4,5,7,8,9
Abdominal		Р	P	P		Ρ	Р		BMDC	Note 2,3,4,5,7,8,9
Intraoperative (Note 6)								-		-,-,-,-,-,-,-
Intraoperative Neurological						·				<u> </u>
Pediatric		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Small Organ (Note 1)		Р	P	P		Р	Р			Note 2,3,4,5,7,8,9
Neonatal Cephalic		Р	Ρ	Р		Р	Р		ВМДС	Note 2,3,4,5,7,8,9
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		Р	Þ	P		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Laparoscopic									· · · · · · · · · · · · · · · · · · ·	
Musculo-skeletal Conventional		Р	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Musculo-skeletal Superficial		Р	P	P		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Other (specify)										· · · · · · · · · · · · · · · · · · ·

N = new indication; P = previously cleared by K072676; E = added under Appendix E

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

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 SieClear multi-view spatial compounding

Note 9 Tissue Equalization Technology

Note 10 Intracardiac imaging

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Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

108076

Section 6 Diagnostic Ultrasound Indications for Use Form

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510(k) Number (if known):

Device Name:

VF8-3 Linear Array Transducer for use with:

**ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

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

						М	ode of Open	ation		
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic								· <del> · - · · · ·</del>		
Fetal		Р	Ρ	P		P	P	_	BMDC	Note 2,3,4,5,7,8,9
Abdominal		Р	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Small Organ (Note 1)		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Neonatal Cephalic		Р	P	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Adult Cephalic									1	
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral									_	
Intravascular										i
Peripheral vessel		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Laparoscopic								***		
Musculo-skeletai Conventional		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Musculo-skeletal Superficial		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5,7,8,9
Other (specify)										<del></del>

N = new indication; P = previously cleared by K072676; E = added under Appendix E

Note	1	For examp	le: breast.	testes.	thyroid.	penis	prostate	etc
11010	•	I O CAUITIP	io. Diodoi	100100	LIIYIOIG,	DOI 119	piostate,	eu.

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

Note 8 SieClear multi-view spatial compounding

Note 9 Tissue Equalization Technology

Note 10 Intracardiac imaging

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Division of Repr	oductive, Abdominal and
Radiological De	vices 1, and an arrival arriva
510(k) Number	L080760

510(k) Number (if known):

Device Name:

P5-1 Phased Array Transducer for use with:

**ACUSON X300 Diagnostic Ultrasound Systems** 

Intended Use:

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	<u> </u>	P	Р	Р	Р	P	Р	7.10	BMDC	Note 2,3,4,5,7,8,9			
Abdominal		Р	Р	Р	P	Р	Р			Note 2,3,5,6,7,8,9			
Intraoperative (Note 6)										1000 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2			
Intraoperative Neurological			-					<u> </u>					
Pediatric		P	P	Р	P	Р	P	·	BMDC	Note 2,3,4,5,7,8,9			
Small Organ (Note 1)						·			S.M.D.O	1010 2,0,4,0,7,0,0			
Neonatal Cephalic		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5,7,8,9			
Adult Cephalic		Р	P	Р	Ρ	Р	Р			Note 2,3,4,5,7,8,9			
Cardiac		Р	Р	P	Р	Р	Р			Note 2,3,4,5,7,8,9			
Transesophageal													
Transrectal													
Transvaginal													
Transurethral													
Intravascular									·-				
Peripheral vessel		Р	P	Р	Р	Р	P		BMDC	Note 2,3,4,5,7,8,9			
Laparoscopic										191 11911 1910			
Musculo-skeletal Conventional													
Musculo-skeletal Superficial						<del></del>		· · · · · · ·					
Other (specify)													

N = new indication; P = previously cleared by K072676; E = added under Appendix E

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

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging Power SieScape panoramic imaging Note 5 Note 6 For example: abdominal, vascular

Contrast agent imaging Note 7

SieClear multi-view spatial compounding Note 8

Tissue Equalization Technology Note 9

Note 10 Intracardiac imaging

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(Division Sign-Off)

Prescription Use (Per 21 CFR 801.109)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

Section 6

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