



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

## MAR 9 2005

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

Re: K050240

Trade Name: ACUSON CV70 Cardiovascular 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 ultrasound transducer

Regulation Number: 21 CFR 870.1200

Regulation Name: Diagnostic intravascular catheter

Regulatory Class: II

Product Code: 90 IYN, IYO, ITX and 74 DQO

Dated: September 30,2004 Received: February 2,2005

#### Dear Mr. Job:

This letter corrects our substantially equivalent letter of February 15, 2005 regarding the missing Regulation Number, Name, and Product Code.

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 CV70 Cardiovascular System, as described in your premarket notification:

### Transducer Model Number

C5-2 Convex Array	7.5L50I Linear Array
C6-2 Convex Array	7.5L50Q Linear Array
C8-5 Convex Array	LAP8-4 Laparoscopic
5.0C50+ Convex Array	P4-2 Phased Sector Array
5.0L45 Linear Array	5.0P10 Phased Sector Array
7.5L70 Linear Array	V5Ms Phased Sector Array TEE
LB5-2 Linear Array	CW2 Continuous Wave Doppler
L10-5 Linear Array	CW5 Continuous Wave Doppler
VF13-5 Linear Array	P9-4 Phased Sector Array
VF13-5SP Linear Array	AcuNav 8F Ultrasound Catheter

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 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 (301) 443-6597 or at its Internet address <a href="http://www.fda.gov/cdrh/dsma/dsmamain.html">http://www.fda.gov/cdrh/dsma/dsmamain.html</a>

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Mancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

K050240

### 510(K) SUMMARY

## ACUSON CV70™ Cardiovascular 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:

FEB 1 5 2005

Siemens Medical Solutions USA, Inc., Ultrasound Division 22010 S.E. 51st Street Issaguah, WA 98029

## **Contact Person:**

Patrick Lynch Regulatory Affairs

Phone: (425) 557-1825 FAX: (425) 391-9198

# Date Prepared:

September 3, 2004

### 2. Proprietary Name:

ACUSON CV70™ Cardiovascular System

#### Common/ Usual Name:

Diagnostic Ultrasound System with Accessories

#### **Classification Name:**

21 CFR 892.1550

Ultrasonic Pulsed Doppler Imaging System
Ultrasonic Pulsed Echo Imaging System
FR # 892.1550
FR # 892.1560
Product Code 90-IYN
Product Code 90-IYO
Product Code 90-IYO
Product Code 90-ITX
Product Code 90-ITX
Product Code 90-DQO

#### 3. Predicate Device:

K042770, 10/20/2004, cleared as ACUSON CV70™ Cardiovascular System. K042593, 10/15/2004, cleared as ACUSON Sequoia™ Diagnostic Ultrasound System.

#### 4. Device Description:

The CV70 is a general purpose, mobile, software-controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bioeffect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in: B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of modes, or Harmonic Imaging, or 3D imaging, on a CRT display.

The CV70 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, 1998 Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment

- AIUM/NEMA UD-2, 1998 Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
  - EN/IEC 60601-1
  - EN/IEC 60601-1-1
  - EN/IEC 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

#### 5. Intended Uses:

The CV70 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 and for analysis packages that provide information that is used for clinical diagnosis purposes.

# 6. Technological Comparison to Predicate Device:

The CV70 is substantially equivalent to the ACUSON CV70, cleared via K042770; and some features of the ACUSON Sequoia, cleared via K042593. 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 and flow, and calculations.

## End of 510(k) Summary

510(k) Number (if known):

Device Name:

**ACUSON CV70 Cardiovascular System** 

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

							ode of Opera	ation		
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic									5,150	Note 2 2 4 5
Fetal		Р	Р	Р	Р	P	Р		BMDC	Note 2,3,4,5
Abdominal		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5
Intraoperative (Note 6)		Р	Р	P		Р	Р		BMDC	Note 3
Intraoperative	<u> </u>	Р	P	P		Р	Р		BMDC	Note 3
Neurological		P	P	P	P	Р	Р		BMDC	Note 2,3,4,5
Pediatric Small Organ	<del>                                     </del>	P	P	P	Р	Р	Р		BMDC	Note 2,3,4,5
(Note 1)		Р	P	P	Р	Р	Р		BMDC	Note 2,3,4,5
Neonatal Cephalic	<b>├</b>	P	<del>                                     </del>	P	P	P	P		BMDC	Note 2,3
Adult Cephalic		I P	P	- <del>'</del>  -	P	P	Р		BMDC	Note 2,3,4,5,7
Cardiac	ļ	P	P	F	P	P	P		BMDC	Note 2,3
Transesophageal	ļ	P	<u>                                   </u>	-	<del>  '                                   </del>	<del> '</del>	<u> </u>		1 1	
Transrectal	<b>_</b>	<del> </del>	ļ.	<b>├</b>	<del> </del> -	<del></del>	<del> </del>	<del> </del>	1	
Transvaginal		<u> </u>	<b> </b>	ļ. —	<del> </del>	<del> </del>	<del> </del>			
Transurethral	<u> </u>	ļ	<u> </u>	<del> </del>	<del> </del>	l N	N	<del>                                     </del>	BMDC	Note 2,3,7,8
Intravascular	<u> </u>	N	N	N	N D	P	P P		BMDC	Note 2,3,4,5
Peripheral vessel	<u> </u>	P	P_	P	P		P	<del> </del>	BMDC	Note 3
Laparoscopic	<u> </u>	<u> </u>	Р	P	↓	Р	<del>                                     </del>	<b> </b>	1	
Musculo-skeletal Conventional		Р	P	Р	Р	Р	Р		BMDC	Note 2,3,4,5
Musculo-skeletal Superficial		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5
Other (specify)	$\top$	N	N	N	N	N_	N N	<u> </u>	BMDC	Note 8

N = new indication; P = previously cleared by FDA (K032111); E = added under Appendix E

41-4- <b>4</b>	For example: breast,	testes	thyroid.	penis.	prostate.	etc.
Note 1	For example: preast,	iesies,	, anyroid,	berna,	prostato,	٠.٠٠

Intracardiac imaging Note 8

> (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,

ancist

and Radiological Devices

510(k) Number.

Ensemble tissue harmonic imaging Note 2

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

B&W SieScape panoramic imaging Note 4

Power SieScape panoramic imaging Note 5

For example: abdominal, vascular Note 6

Contrast agent imaging Note 7

510(k) Number (if known):

Device Name:

C5-2 Convex Array Transducer for use with:

**ACUSON CV70 Cardiovascular System** 

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							P		BMDC	Note 2,3,4,5
Fetal	l	Р	Р	Р		P	P		BMDC	Note 2,3,4,5
Abdominal		P	P	Р		Р	P		BIVIDO	(1010 2,0,1,0
Intraoperative Abdominal										
Intraoperative Neurological									BMDC	Note 2,3,4,5
Pediatric		Р	P	P	ļ	Р	Р	<del> </del>	BIVIDO	11016 2,0,7,0
Small Organ			<u> </u>	<b>1</b>	<u> </u>		ļ		<del>-{</del>	<del> </del>
Neonatal Cephalic	$\Gamma$		<u> </u>		ļ		<u> </u>		-}	
Adult Cephalic				<u> </u>	ļ			<del> </del>	<del> </del>	
Cardiac			<u> </u>		ļ	ļ <u> </u>		<del> </del>	<del> </del>	
Trans-esophageal	<u> </u>	<u> </u>	ļ	ļ	<b></b>	<u> </u>		ļ — — — — — — — — — — — — — — — — — — —	<del> +</del>	
Transrectal			<u> </u>	<u> </u>		ļ	<del>                                     </del>	ļ	1	
Transvaginal			ļ	ļ	ļ	ļ	<del> </del>	ļ —	<del> </del>	
Transurethral		<u> </u>	↓	ļ	ļ	<del> </del>	ļ.——	<del> </del>	<del> </del>	
Intravascular		<u> </u>	<u> </u>		ļ	<del> </del>	P	<b> </b>	BMDC	Note 2,3,4,5
Peripheral vessel		Р	P	P	<del> </del>	P_	<u> </u>	<del> </del>	- DIVIDO	11010 2,01 110
Laparoscopic	<u> </u>	1	<del> </del>	1	<b></b> _	<del> </del>	<del> </del>	<del> </del>	<del>  </del>	
Musculo-skeletal Conventional					ļ					
Musculo-skeletal Superficial						<u> </u>				
Other (Specify)							= addad un		<u> </u>	

N = new indication; P = previously cleared by FDA (K032111); E = added under Appendix E

emble tissue	harmonic	imaging
	emble tissue	emble tissue harmonic

Note 3 3D imaging

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

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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):

Device Name:

C6-2 Convex Array Transducer for use with:

ACUSON CV70 Cardiovascular System

Intended Use:

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

						Me	ode of Opera	ation		
Clinical Application	Α	8	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										<del></del>
Fetal		Р	Р	Р		P	Р		BMDC	Note 2,3,4,5
Abdominal		Р	P	Р		P	Р		BMDC	Note 2,3,4,5
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5
Small Organ	]	I	Ī							
Neonatal Cephalic		<u> </u>	<u> </u>	1	<u> </u>					
Adult Cephalic		<u> </u>							ļ	
Cardiac		<u> </u>		<u> </u>					<u> </u>	
Trans-esophageal		<u> </u>		ļ					<u> </u>	
Transrectal	L			<u></u>						
Transvaginal	Ī	<u> </u>					ļ		<b></b>	
Transurethral				ļ					<b></b>	
Intravascular		<u> </u>		ļ			<u> </u>	ļ. —		111 0015
Peripheral vessel		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5
Laparoscopic			<u> </u>				<u> </u>	ļ <u> </u>	<b></b>	<del></del>
Musculo-skeletal Conventional										
Musculo-skeletal Superficial		_		ļ .			<u></u>			
Other (specify)							ļ <u> </u>	<u></u>		

N = new indication; P = previously cleared by FDA (K032111); E = added under Appendix E

Note 2 Ensemble tissue harmonic imag	my	
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Note 3 3D imaging

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

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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):

Device Name:

C8-5 Convex Array Transducer for use with:

**ACUSON CV70 Cardiovascular System** 

Intended Use:

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

						М	ode of Oper	ation		
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthaimic										
Fetal									<u> </u>	
Abdominal		Р	Р	Р		Р	P		BMDC .	Note 2,3,4,5
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	Р	Р		Р	Р		BMDC	Note 2,3,4,5
Small Organ (Note 1)		Р	Р	Р		Р	P		BMDC	Note 2,3,4,5
Neonatal Cephalic		Р	Р	Р		Р	P		BMDC	Note 2,3,4,5
Adult Cephalic										
Cardiac		E	E	E		E	E		BMDC	Note 2,3,4,5
Transesophageal										
Transrectal										
Transvaginal		<u>.</u>								
Transurethral	1									
Intravascular										
Peripheral vessel			·		[]					
Laparoscopic				<b>!</b>					<b>!</b>	
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5
Musculo-skeletal Superficial		Е	Е	E		Е	E		BMDC	Note 2,3,4,5
Other (specify)										

N = new indication; P = previously cleared by FDA (K032111); E = added under Appendix E

Note 1	For example:	breast, testes,	, thyroid, pe	nis, prostate, et	C.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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

510(k) Number (if known):

Device Name:

5.0C50+ Convex Array Transducer for use with:

**ACUSON CV70 Cardiovascular System** 

Intended Use:

Diagnostic 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		Р	ը	Р	Р	P	P		BMDC	Note 2,3,4,5
Abdominal		Р	Р	Р	P	Р	Р		BMDC	Note 2,3,4,5
Intraoperative Abdominal Intraoperative Neurological				:						
Pediatric		P	P	Р	Р	Р	Р		BMDC	Note 2,3,4,5
Small Organ (Note 1)		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5
Neonatal Cephalic									ļ	
Adult Cephalic									<del> </del>	
Cardiac		Ì							<b> </b>	
Transesophageal				<u> </u>			ļ		ļ	
Transrectal		<u> </u>							<del>                                     </del>	
Transvaginal			<u> </u>	ļ					<del> </del>	
Transurethral						<b></b>			<u> </u>	
Intravascular			L	<u> </u>	ļ				1	N-4- 0 2 4 C
Peripheral vessel	<u></u>	Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5
Laparoscopic		<u> </u>		ļ	<b>.</b>	<u> </u>			<del> </del>	
Musculo-skeletal Conventional		E	Е	E	E	E	E		BMDC	Note 2,3,4,5
Musculo-skeletal Superficial		E	E	Ε	Е	Ε	E		BMDC	Note 2,3,4.5
Other (specify)						l			<u> </u>	

N = new indication; P = previously cleared by FDA (K032111); E = added under Appendix E

Note 1	For example: breast,	testes, thyroid,	, penis, prostate, et	C.
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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number \_\_\_

Ensemble tissue harmonic imaging Note 2

Note 3 3D imaging

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

510(k) Number (if known):

Device Name:

5.0L45 Linear Array Transducer for use with: **ACUSON CV70 Cardiovascular System** 

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									<del> </del>	
Fetal					ļ <u>.</u>				BMBC	Note 2,3,4,5
Abdominal		Р	P	Р	P	Р	Р		BMDC	Note 2,3,4,3
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric	<u> </u>	ļ	ļ	<del> </del>	<del> </del>	<del></del>	<del>                                     </del>		<del>                                     </del>	
Small Organ (Note 1)		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5
Neonatal Cephalic		<u> </u>		ļ	ļ		<del> </del>		<del>                                     </del>	
Adult Cephalic		<u> </u>	<u> </u>	<u> </u>	<b> </b>		ļ		<del></del>	
Cardiac	<u> </u>	<u> </u>			ļ		<del> </del>		<del> </del>	
Transesophageal			<u> </u>	ļ	<u> </u>		ļ	ļ <u> </u>	<del>                                     </del>	
Transrectal	<u> </u>	<u> </u>		<u> </u>	<u> </u>		<u> </u>		<del> </del>	
Transvaginal	<u> </u>	<u> </u>	<u> </u>	<b></b>	<u> </u>			<del> </del>	<del>-  -</del>	
Transurethral			<u> </u>		ļ				<del></del>	
Intravascular		<u> </u>	<u> </u>	<u> </u>	<del></del>		<del> </del>	<del> </del>	I BUDG	Note 2,3,4,5
Peripheral vessel		P	Р	P	P	Р	Р	<u> </u>	BMDC	110te 2,3,4,5
Laparoscopic	<u> </u>	1	<u> </u>	<u> </u>	<u> </u>		ļ	<b> </b>	<u> </u>	
Musculo-skeletal Conventional		Р	Р	Р	Р	Р	P		BMDC	Note 2,3,4,5
Musculo-skeletal Superficial					<u> </u>					
Other (specify)					<u> </u>	<u> </u>	<u> </u>	<u> </u>	<u> </u>	

N = new indication; P = previously cleared by FDA (K032111); E = added under Appendix E

Note 1	For example: breast, test	es, thy	roid,	penis,	prostate,	etc.

(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 -

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

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

510(k) Number (if known):

Device Name:

7.5L70 Linear Array Transducer for use with: **ACUSON CV70 Cardiovascular System** 

Intended Use:

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

						Mo	ode of Opera	ation		
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic									<del>├</del> ───┤	
Fetal		L	L		ļ				<del> </del>	
Abdominal							<b> </b>		<del> </del>	
Intraoperative Abdominal										
Intraoperative Neurological							P		BMDC	Note 3,4,5
Pediatric		P	Р	Р	1	P	<u>'</u>	<b></b>	<del> </del>	
Small Organ (Note 1)		Р	P	Р		P	P		BMDC	Note 3,4,5
Neonatal Cephalic		<u> </u>		<u> </u>	ļ	ļ <u> </u>			<del></del>	
Adult Cephalic		<u> </u>	ļ	ļ	↓	<u> </u>	<del> </del>		<del> </del>	··
Cardiac		<u> </u>		ļ	ļ <u></u>		<del> </del>	<del> </del>	<del>                                     </del>	
Transesophageal		1		<u> </u>	ļ		<del> </del> -		<del> </del>	
Transrectal	<u> </u>		ļ	ļ	<b> </b>	ļ			<del>                                  </del>	
Transvaginal		<u> </u>	1	<u> </u>	ļ		ļ	ļ	<del> </del>	
Transurethral		<u> </u>		<del>                                     </del>	<del> </del>	<del> </del>	ļ	<del> </del>	<del> </del>	
Intravascular	ļ		<u> </u>	<del> </del> _	<del> </del>	<u> </u>	<u>-</u>	<b> </b>	BMDC	Note 3,4,5
Peripheral vessel		E	E	E		E	<del></del>	<del> </del>	+ BIMIDO	11010 01110
Laparoscopic	<u> </u>	<u> </u>	<u> </u>	$\perp$	<del> </del>	<del> </del>	<del> </del>	<del> </del>	<del></del>	
Musculo-skeletal Conventional		P	Р	Р		Р	Р		BMDC	Note 3,4,5
Musculo-skeletal Superficial		Р	P	Р		Р	Р		BMDC	Note 3,4,5
Other (specify)	1	T		1				<u></u>		

N = new indication; P = previously cleared by FDA (K032111); E = added under Appendix E

Note 1	For example: breast,	testes.	thyroid,	penis,	prostate,	etc.
Note 1	For example, Dieday,	LCOLCO,	,	Po.mo!	h	

Power SieScape panoramic imaging

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices KOSD 24D

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

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

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

510(k) Number (if known):

Device Name:

LB5-2 Linear Array Transducer for use with:

**ACUSON CV70 Cardiovascular System** 

Intended Use:

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

						Мо	de of Opera	tion		
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Р	Р		p.	Р		BMDC	Note 4,5
Abdominal		Р	Р	Р		Р	Р		BMDC	Note 4,5
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA (K032111); E = added under Appendix E

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

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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):

Device Name:

L10-5 Linear Array Transducer for use with:

**ACUSON CV70 Cardiovascular System** 

Intended Use:

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		l								
Fetal										
Abdominal		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5
Small Organ (Note 1)		Р	Р	Р		Р	Р	•	BMDC	Note 2,3,4,5
Neonatal Cephalic										
Adult Cephalic					ļ				1 1	
Cardiac										
Trans-esophageal							ļi			
Transrectal										
Transvaginal				ļ						
Transurethral			<u> </u>		<b></b>					
Intravascular		<u> </u>								
Peripheral vessel		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5
Laparoscopic										
Musculo-skeletal Conventional		Р	Р	Р		Р	Р	-,	вмос	Note 2,3,4,5
Musculo-skeletal Superficial		Р	Ρ	Р		Р	Р		BMDC	Note 2,3,4,5
Other (specify)									<u>                                       </u>	

N = new indication; P = previously cleared by FDA (K032111); E = added under Appendix E

						4 - 4 -	-4-
Note 1	For example:	breast.	testes.	thyroid.	penis.	prostate.	etc.

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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,

Radiological Devices

aki Number \_

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

510(k) Number (if known):

Device Name:

VF13-5 Linear Array Transducer for use with:

**ACUSON CV70 Cardiovascular System** 

Intended Use:

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

				- :	<del></del>	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									<u> </u>	
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		Р	Р	Р	Р	Р	Р		BMDC	Note 3,4,5
Small Organ (Note 1)		Р	Р	Р	Р	Р	Р		BMDC	Note 3,4,5
Neonatal Cephalic										·
Adult Cephalic										
Cardiac										
Transesophageal		i		<u> </u>						
Transrectal									11	
Transvaginal								<del> </del>		
Transurethral										
Intravascular				<u> </u>						
Peripheral vessel		Р	Р	Р	Р	Р	P		BMDC	Note 3,4,5
Laparoscopic										
Musculo-skeletal Conventional		Р	P	Р	Р	Þ	Р		вмос	Note 3,4,5
Musculo-skeletal Superficial		Р	Р	P	Р	Р	Р		вмос	Note 3,4,5
Other (specify)										

N = new indication; P = previously cleared by FDA (K032111); E = added under Appendix E

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

Note 3 3D imaging

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off) \( \int \)
Division of Reproductive, Abdominal,

and Radiological Devices

had(k) Number \_\_\_\_\_

510(k) Number (if known):

Device Name:

VF13-5SP Linear Array Transducer for use with:

**ACUSON CV70 Cardiovascular System** 

Intended Use:

Diagnostic 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									<del> </del>	
Abdominal							<b> </b>		<del> </del>	
Intraoperative (note 6)		Р	Р	Р		P	P		BMDC	Note 3
Intraoperative Neurological		Р	Р	Р		Р	Р		BMDC	Note 3
Pediatric		Р	Р	Р		P	P		BMDC	Note 3
Small Organ (Note 1)		Р	Р	Р		Р	Р		BMDC	Note 3
Neonatal Cephalic							ļ <u> </u>		<del>                                     </del>	
Adult Cephalic			<u> </u>		<u> </u>		ļ		<del>                                     </del>	
Cardiac			<u> </u>	<u> </u>	<u> </u>	ļ	<u> </u>		<del>                                     </del>	
Transesophageal		<u> </u>			ļ	ļ	ļ. <u> </u>		<del> </del>	
Transrectal		ļ <u>.</u>	<u> </u>	ļ	<u> </u>				<del> </del>	
Transvaginal	l	<u> </u>	<u> </u>		ļ		<del> </del>		<del> </del>	
Transurethral					ļ		<del> </del>		<del>                                     </del>	· · · · · · · · · · · · · · · · · · ·
Intravascular		<u> </u>	Ļ	<b>└</b>	ļ	<del> </del>	P	ļ. ———	BMDC	Note 3
Peripheral vessel		P	P	Р	<del>↓</del> -	Р	<del> !'</del>	<b> </b>	BIVIDO	11016 5
Laparoscopic	<u> </u>	<u> </u>	1_	<u> </u>	<del>  </del>	<b> </b>		<del> </del>	<del>                                     </del>	
Musculo-skeletal Conventional	ļ	Р	P	Р	<u> </u>	Р	Р		BMDC	Note 3
Musculo-skeletal Superficial		Р	Р	Р	<u> </u>	Р	Р		BMDC	Note 3
Other (specify)		1	T			<u> </u>				

N = new indication; P = previously cleared by FDA (K032111); E = added under Appendix E

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

Note 3 3D imaging

Note 6 For example: abdominal, vascular

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sigh-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number

510(k) Number (if known):

Device Name:

7.5L50I Linear Array Transducer for use with:

**ACUSON CV70 Cardiovascular System** 

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								<del></del>		
Fetal		L							BUDG	Note 3,4,5
Abdominal		Р	Р	Р		Р	Р		BMDC	
Intraoperative (Note 6)		Р	Р	Р		P	Р		BMDC	Note 3,4,5
Intraoperative Neurological										
Pediatric		<u> </u>		<b></b>	ļ					
Small Organ (Note 1)	<u> </u>	Р	Р	Р		P	Р		BMDC	Note 3,4,5
Neonatal Cephalic		1		<u> </u>	ļ		<u> </u>		<del>}</del>	<del></del>
Adult Cephalic	<u> </u>	<u> </u>	<u> </u>	<u> </u>	ļ		<del> </del>		<del> </del>	
Cardiac		<u> </u>		ļ	ļ		<del> </del>		<del> </del>	<u> </u>
Transesophageal			ļ	<b> </b>		ļ <u> </u>	ļ		<del> </del>	
Transrectal		<u> </u>	<u> </u>	<u> </u>			ļ		<del> </del>	
Transvaginal		<u> </u>	<u> </u>	<u> </u>	<del> </del>		ļ		<del> </del>	
Transurethral			ļ	<u> </u>	<del>            _   _</del>		<del> </del>	<del>                                     </del>	+	
Intravascular				ļ <u>.</u>	<u> </u>		+ -	ļ	BMDC	Note 3,4,5
Peripheral vessel	<u> </u>	P	₽.	P	ļ. —	Р	P	<u> </u>	- PINIOC	140(6 0,4,0
Laparoscopic	<u> </u>	<u> </u>	<u> </u>	<u> </u>	<del> </del>	<u> </u>	<del> </del>			
Musculo-skeletal Conventional		Р	Р	Р	<u> </u>	Р	Р		BMDC	Note 3,4,5
Musculo-skeletal Superficial			<u></u>							
Other (specify)				1	1	L	<u> </u>	<u> </u>	<u> </u>	- <u>-</u>

N = new indication; P = previously cleared by FDA (K032111); E = added under Appendix E

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

K050240

Note 3 3D imaging

Note 4 B&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

510(k) Number (if known):

Device Name:

7.5L50Q Linear Array Transducer for use with:

**ACUSON CV70 Cardiovascular System** 

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										
Fetal				<u> </u>					<u> </u>	· · · · · · · · · · · · · · · · · · ·
Abdominal		Р	Р	Р		Р	Р		BMDC	Note 3,4,5
Intraoperative (Note 6)		Р	Р	Р		Р	P		вмос	Note 3,4,5
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		Р	Р	Р		Р	Р		вмос	Note 3,4,5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal									<u> </u>	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		Р	Р	Р		Р	Р		BMDC	Note 3,4,5
Laparoscopic									ļ	<u>.</u> .
Musculo-skeletal Conventional		Р	P	Р		P	Р		BMDC	Note 3,4,5
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA (K032111); E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis	: nrostate	etc

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off) / Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number \_\_\_

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

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

For example: abdominal, vascular Note 6

510(k) Number (if known):

Device Name:

LAP8-4 Laparoscopic Transducer for use with:

**ACUSON CV70 Cardiovascular System** 

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)		Р	P	Р		P	Р		BMDC	Note 3,4,5	
Intraoperative Neurological											
Pediatric											
Small Organ							!				
Neonatal Cephalic									<u> </u>		
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal									l	·	
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic		Р	Ρ	Р		Р	Р		BMDC	Note 3,4,5	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA (K032111); E = added under Appendix E

Note 3 3D imaging

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

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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

5+O(k) Number \_\_\_\_\_

KU00240

510(k) Number (if known):

Device Name:

P4-2 Phased Sector Array Transducer for use with:

**ACUSON CV70 Cardiovascular System** 

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									ļl.			
Fetal									<del> </del> +			
Abdominal		Р	Р	Р	Р	Р	Р		BMDC	Note 2,3		
Intraoperative Abdominal												
Intraoperative Neurological												
Pediatric	<u> </u>			ļ					<del>  -</del>			
Small Organ									<del>                                     </del>			
Neonatal Cephalic				<u> </u>	<u> </u>				1 100	Maka 0.0		
Adult Cephalic		Р	Р	P	Р	Р	P		BMDC	Note 2,3		
Cardiac		Р	P	P	Р	Р	Р		BMDC	Note 2,3,7		
Transesophageal	L			ļ			<u> </u>		<del> </del>			
Transrectal				<b></b>		<u> </u>	<u> </u>		<del>                                     </del>			
Transvaginal	L			<b> </b>	<u> </u>		ļ		<del> </del>			
Transurethral		<u> </u>	<u> </u>	ļ	ļ	ļ	ļ	ļ	<del> </del>	<del></del>		
Intravascular			<u> </u>	<u> </u>	ļ	L	ļ		1 +			
Peripheral vessel		<u></u>		ļ	<u> </u>		ļ		<del>                                     </del>			
Laparoscopic		<u> </u>		ļ			<u> </u>	ļ	<del>  </del>			
Musculo-skeletal Conventional												
Musculo-skeletal Superficial				ļ				<u> </u>		<u></u> -		
Other (specify)					<u> </u>	<u> </u>			<u> </u>			

N = new indication; P = previously cleared by FDA (K032111); E = added under Appendix E

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 7 Contrast agent imaging

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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

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510(k) Number (if known):

Device Name:

5.0P10 Phased Sector Array Transducer for use with:

**ACUSON CV70 Cardiovascular System** 

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	=								BMDC	Note 2
Fetal		Р	P	Р	Р	Р	Р		BMDC	Note 2
Abdominal		Р	Р	Р	Р	Р	Р		BMDC	1101.0 2
Intraoperative Abdominal							<u> </u>			
Intraoperative Neurological							 		BMDC	Note 2
Pediatric		P	P	Р	P	Р	<del>                                     </del>		DIVIDO	,,,,,,,
Small Organ		<u> </u>	<u> </u>	ļ	<u> </u>		P		BMDC	Note 2
Neonatal Cephalic		P	I P	Р	P	Р_	<del>                                     </del>	<b></b>	- BIVIDO	110.0 -
Adult Cephalic		<u> </u>	<u> </u>		<del> </del> _	<del> </del>	P		BMDC	Note 2,7
Cardiac	<u> </u>	P	P	P	P	Р_	<u> </u>		BINIDO	11015
Transesophageal	<u> </u>	1_	ļ	<b>!</b> — —	<b> </b>	ļ <u>.</u>	<del> </del>		<del> </del>	
Transrectal		ļ	<b> </b>	ļ	<del> </del>		<del> </del>		<del>  -   -</del>	
Transvaginal	<u> </u>	<u> </u>	↓	<b> </b>	<del> </del>	<del> </del>	<del> </del>	ļ — — — ·	<del>                                     </del>	
Transurethral		ļ	↓	<del> </del>	<del> </del>	<del> </del>	<del> </del>	ļ	<del>                                     </del>	
Intravascular		<u> </u>	ļ	<del> </del>	<del> </del>	<del> </del>	<del>                                      </del>	<u> </u>	<del>                                     </del>	
Peripheral vessel	ļ	ļ	<u> </u>	<b>↓</b>	<del>                                      </del>	<del> </del>		<del>                                     </del>	<del>-  </del>	
Laparoscopic	1	↓_	<u> </u>	1	┥	<del> </del>	<del> </del>	<del> </del>		
Musculo-skeletal Conventional					<u> </u>					
Musculo-skeletal Superficial	ļ			<u> </u>	<u> </u>	<u> </u>	ļ		ļ <u> </u>	
Other (specify)				<u></u>		<u> </u>	1	der Append	<u> </u>	_ <del></del>

N = new indication; P = previously cleared by FDA (K032111); E = added under Appendix E

Note 2 Ensemble tissue harmonic imaging

Note 7 Contrast agent imaging

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off) Division of Reproductive, Abdominal,

್ಲಾ Padiological Devices

510(k) Number (if known):

Device Name:

V5Ms Phased Sector Array TEE Transducer for use with:

**ACUSON CV70 Cardiovascular System** 

Intended Use:

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									<b> </b>	
Fetal	<u></u>			ļ <u>-</u>					<del> </del>	
Abdominal			<u> </u>	ļ <u>.</u>					<del>                                     </del>	
Intraoperative Abdominal			L						ļ	
Intraoperative Neurological										
Pediatric					<u> </u>			<u> </u>	<del> </del>	
Small Organ (Specify)			<u> </u>							
Neonatal Cephalic	[	l	<u> </u>	<b>_</b>	<u> </u>	ļ		ļ. <u></u>		
Adult Cephalic					<u> </u>		<u> </u>	<u> </u>	<del>                                     </del>	
Cardiac			<u> </u>		ļ		<u> </u>		D1400	Note 2.2
Trans-esophageal	<u> </u>	P_	P	P	P	P	P		BMDC	Note 2,3
Transrectal		<u> </u>	<u> </u>	<u> </u>	<u> </u>				<del> </del>	
Transvaginal			<u> </u>		<u> </u>		ļ	-	<del> </del>	
Transurethral	ļ		<u> </u>		<b> </b>	ļ		<del> </del>	<del> </del>	
Intravascular		ļ <u>.</u>	ļ	<u> </u>	<u> </u>		<u> </u>	ļ	<del> </del>	
Peripheral vessel		<u> </u>		.	ļ		<del> </del>		<del> </del>	·
Laparoscopic		<u> </u>	1	<u> </u>	<del> </del>		ļ	<u> </u>	<del> </del>	
Musculo-skeletal Conventional					<u> </u>					
Musculo-skeletal Superficial									<u> </u>	
Other (specify)			<u>L</u> .	1	<u> </u>	<u> </u>		<u> </u>	<u></u>	

N = new indication; P = previously cleared by FDA (K032111); E = added under Appendix E

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

To ision of Reproductive Abdominar

K050240

510(k) Number (if known):

Device Name:

CW2 Continuous Wave Doppler Transducer for use with:

**ACUSON CV70 Cardiovascular System** 

Intended Use:

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

						Me	ode of Opera	ation		<u></u>
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal	]								ļi	
Abdominal									<u> </u>	
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric				<u> </u>					<b></b>	
Small Organ	[									
Neonatal Cephalic			<u> </u>	<u> </u>					<u> </u>	
Adult Cephalic									<u> </u>	
Cardiac	<u> </u>				Р					
Trans-esophageal				<u></u>				ļ	<del> </del>	
Transrectal		<u> </u>	<u> </u>	<u> </u>					ļ l	
Transvaginal	Ι΄		<u> </u>	<u> </u>					1	
Transurethral	<u> </u>							<u> </u>	ļ	
Intravascular			<u> </u>						ļ	<u>.</u>
Peripheral vessel							ļ <u> </u>	<u></u>	<u> </u>	
Laparoscopic				<u> </u>			·		ļ	
Musculo-skeletal Conventional										,
Musculo-skeletal Superficial										
Other (specify)									11	

N = new indication; P = previously cleared by FDA (K032111); E = added under Appendix E

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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):

Device Name:

CW5 Continuous Wave Doppler Transducer for use with:

**ACUSON CV70 Cardiovascular System** 

Intended Use:

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

		Mode of Operation									
Clinical Application	А	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic						•					
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ											
Neonatal Cephalic											
Adult Cephalic											
Cardiac									l j		
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel					P						
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA (K032111); E = added under Appendix E

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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

⇒1Ω(k) Number \_\_\_\_

510(k) Number (if known):

Device Name:

P9-4 Phased Sector Array Transducer for use with:

**ACUSON CV70 Cardiovascular System** 

Intended Use:

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		Ρ	Ρ	Р	Р	Р	Р		BMDC	Note 2
Abdominal		Р	۵	P	P	Р	Р		BMDC	Note 2
Intraoperative Abdominal										
Intraoperative Neurological		Ω.	P	Р		Р	Р		BMDC	Note 2
Pediatric		Ρ	Р	Р	Р	Р	Р		BMDC	Note 2
Small Organ		Ð	P	Р	Р	Р	Р			
Neonatal Cephalic		P	Р	Р	P	Р	Р		BMDC	Note 2
Adult Cephalic		Ρ	P	Р	Р	Р	Р		<u> </u>	
Cardiac		Р	Р	Р	Р	Р	Р	·	BMDC	Note 2,7
Transesophageal										
Transrectal									<u> </u>	
Transvaginal			L							
Transurethral									ļ	
Intravascular								<u></u>	1	
Peripheral vessel		Р	Ρ	P	P	P	Р		BMDC	Note 2
Laparoscopic									ļ	
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA (K042044); E = added under Appendix E

Note 2	Ensemble	fissue	harmonic	imaging
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Note 7 Contrast agent imaging

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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):

Device Name:

AcuNav 8F ultrasound catheter for use with:

**ACUSON CV70 Cardiovascular System** 

Intended Use:

Intracardiac and intravascular visualization of cardiac and great vessel anatomy and physiology, and visualization of other devices in the heart as

follows:

	<del></del>	Mode of Operation									
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic									<del> </del>		
Fetal									<del>                                     </del>		
Abdominal								<u> </u>	<del> </del>		
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric					<u> </u>		ļ <u> </u>		<del> </del>		
Small Organ				ļ <u></u>					<del> </del>		
Neonatal Cephalic		<u> </u>		<b> </b>	<u> </u>		<u> </u>		<del>  </del>		
Adult Cephalic		<u> </u>		<u> </u>	<u> </u>				BMDC	Note 2,7	
Cardiac	<u> </u>	N	N	N_	N	N	N N		BMDC	Note 2,7	
Transesophageal		<u> </u>	<u> </u>	<u> </u>	<u> </u>		<b>_</b>		<del>    -</del>		
Transrectal				<u> </u>	ļ. <u> </u>	ļ	<del> </del>	<u> </u>	<del>                                     </del>		
Transvaginal	ļ	<u> </u>	ļ	<del> </del>	<u> </u>	ļ	<del> </del>		<del> </del>	<u></u>	
Transurethral	ļ		<u> </u>	<del> </del>	<del> </del>	N	- N		BMDC	Note 2,7	
Intravascular	<u> </u>	N	N	N_	N	N	N		BIVIDO	11010 2.1.	
Peripheral vessel		<u> </u>	<b></b>		<del>                                     </del>	ļ . <del></del>	<del> </del>	<del> </del>	<del> </del>		
Laparoscopic		<u> </u>	ļ <u>.</u>	↓	<del> </del>		<del> </del>		+		
Musculo-skeletal Conventional	_								1		
Musculo-skeletal Superficial									8450	Nato 2 2 7 9	
Other (specify)		N	N	N	N	N_	N N		BMDC	Note 2,3,7,8	

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

Note 2 Ensemble tissue harmonic imag	gınç	g
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Note 3 3D imaging

Note 7 Contrast agent imaging Note 8 Intracardiac Imaging

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