K0420f4

# AUG 1 3 2004 SECTION 11

# 510(k) Summary of Safety and Effectiveness

Sponsor: Siemens Medical Solutions USA, Inc., Ultrasound Division

1230 Shorebird Way

P.O. Box 7393

Mountain View, California 94039-7393

Contact Person: Patrick Lynch

Regulatory Affairs

Telephone: 425-557-1825

Fax: 425-391-9198

Submission Date: July 28, 2004

Device Name: ACUSON CV70<sup>TM</sup> Cardiovascular System

Common Name: Diagnostic Ultrasound System with Accessories

Classification:

Regulatory Class: II Review Category: Tier II Classification Panel: Radiology

21 CFR 892.1550

	<u>FR #</u>	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

#### Predicate Devices:

# K032111 (July 18, 2003) cleared as ACUSON CV70™ Cardiovascular System.

### **Device Description:**

The CV70 system is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to our current product that is already cleared for USA distribution under the following 510(k) Premarket Notification number:

• ## K032111 (July 18, 2003) cleared as ACUSON CV70<sup>TM</sup> Cardiovascular System.

The CV70 Cardiovascular System has been designed to conform to the following product safety standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-2, 1998, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- AIUM/NEMA UD-3, 1998, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- 93/42/EEC Medical Device Directive
- Safety and EMC Requirements for Medical Equipment
- EN 60601-1
  - EN 60601-1-1
  - EN 60601-1-2
- ISO 10993 Biocompatibility
- The system's acoustic output is in accordance with ALARA principle (as low as reasonably achievable)

#### Intended Use:

The CV70 platform is intended for use in the following applications:

Abdominal, Intraoperative, Small Parts, Transcranial, Cardiac, Transesophageal, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications, and intended uses as defined in the FDA guidance document.

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

# Technological Comparison to Predicate Device:

The CV70 is substantially equivalent in its technologies and functionality to the CV70 Cardiovascular System that is already cleared under 510(k) premarket notification number K032111.

The CV70 functions in the same manner as other diagnostic ultrasound systems, in that they transmit ultrasonic energy into the body via a transducer. In the body, acoustic impedance of different tissues reflect different amounts of ultrasound energy back to the transducer, where post processing of received echoes is performed to generate two-dimensional on-screen images of anatomic structures and fluid flow within the body. Doppler principles are used to process reflected ultrasound energy to display moving blood as a spectrum, or as color-coded two-dimensional images. The predicate device listed above, allows for specialized measurements of structures and flow, and provide various calculations' functions.





Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

# AUG 1 3 2004

Mr. Patrick Lynch Regulatory Affairs Siemens Medical Solutions USA, Inc. 1230 Shorebird Way P.O. Box 7393 MOUNTAIN VIEW CA 94039-7393

Re: K042044

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 transducer

Regulatory Class: II

Product Code: 90 IYN, IYO, and ITX

Dated: July 28, 2004 Received: July 30, 2004

### Dear Mr. Lynch:

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<sup>TM</sup> Cardiovascular System, as described in your premarket notification:

### Transducer Model Number

C5-2 Convex Array
C6-2 Convex Array
C8-5 Convex Array

5.0C50+ Convex Array 5.0L45 Linear Array 7.5L70 Linear Array LB5-2 Linear Array
L10-5 Linear Array
VF13-5 Linear Array
VF13-5SP Linear Array
7.5L50I Linear Array
LAP8-4 Laparoscopic

P4-2 Phased Sector Array
5.0P10 Phased Sector Array
V5Ms Phased Sector Array TEE
CW2 Continuous Wave Doppler
CW5 Continuous Wave Doppler
P9-4 Phased Sector 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 Federal Register. Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This 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 80), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-

4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

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

Sincerely yours,

Vancy Choglon
Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosures

510(k) Number (if known):

Device Name:

**ACUSON CV70 Cardiovascular System** 

Intended Use:

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

<u> </u>						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> -								5,420	11-1-0045
Fetal		Р	Р	P_	Ρ	P	P		BMDC	Note 2,3,4,5
Abdominal		Р	P	Р_	Р	Р	Р		BMDC	Note 2,3,4,5
Intraoperative (Note 6)		Р	Р	Р		Р	Р		BMDC	Note 3
Intraoperative Neurological		Р	Р	P		Р	Р		вмрс	Note 3
Pediatric		P	P	Р	Р	P	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		Р	Ρ	Р	P	Р	Р		BMDC	Note 2,3,4,5
Adult Cephalic	1	P	Р	P	Р	Р	Р		BMDC	Note 2,3
Cardiac	1-	P	P	P	Р	Р	Р		BMDC	Note 2,3,4,5,7
Transesophageal	<del> </del>	P	Р	Р	Р	Р	P		BMDC	Note 2,3
Transcectal	1	1		1	<u> </u>					
Transvaginal	1	1								
Transurethral	<del>                                     </del>			1						
Intravascular	1 -	1 -							<u> </u>	
Peripheral vessel	1	P	P	Р	Р	Р	Р		BMDC	Note 2,3,4,5
Laparoscopic	1	P	Р	Р		Р	Р		BMDC	Note 3
Musculo-skeletal Conventional		Р	Р	P	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)	1	1	1						<u>.l</u>	

N = new indication; P = previously cleared by FDA; 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 ...

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

Note 4 8&W SieScape panoramic imaging

Note 5 Power SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 7 Contrast agent imaging

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:

	T	Mode of Operation									
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic									100	N-4- 2 2 4 5	
Fetal		P	P	Р		P	Р	. <del></del>	BMDC	Note 2,3,4,5	
Abdominal		Р	Р	P		Р.	Р		BMDC	Note 2,3,4,5	
Intraoperative Abdominal									ļ		
Intraoperative Neurological									2110	N. 1. 2. 2. 4. 5	
Pediatric		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5	
Small Organ				<u> </u>	ļ		<u></u>		<del>                                     </del>		
Neonatal Cephalic		Ĭ		<u> </u>							
Adult Cephalic		<u> </u>		ļ			<u> </u>	·			
Cardiac		<u> </u>	<u> </u>	<u> </u>		ļ					
Trans-esophageal			<u> </u>		ļ						
Transrectal		<u> </u>		ļ	ļ			<u> </u>	<del>                                     </del>		
Transvaginal		<u> </u>	ļ	ļ	<u> </u>				<del> </del>		
Transurethral	<u> </u>	<u> </u>	↓	<del> </del>	ļ		ļ				
Intravascular			ļ <u>.</u>	<b>_</b>	ļ	<u> </u>	<del> </del>		PARC	Note 2 2 4 5	
Peripheral vessel		P	P	P	<u> </u>	Р	P	<del> </del>	BMDC	Note 2,3,4,5	
Laparoscopic		<u> </u>	<u> </u>	ļ			<u> </u>	ļ	<del> </del>		
Musculo-skeletal Conventional							ļ				
Musculo-skeletal Superficial											
Other (Specify)	1			<u></u>	<u></u>	<u> </u>	ndor ( ppepe	<u> </u>			

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

Mana O	Ensemble	ficeup.	harmonic	imadiba
NOR	Fuseinoie	ussuc	Harmonic	minaging

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

Note 3 3D imaging

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

Note 5 Power SieScape panoramic imaging

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:

	Mode of Operation									
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic									D14D0	Note 2.2.4.5
Fetal		Р	Р	Р		P	P		BMDC	Note 2,3,4,5
Abdominal		P	Р	P		Р	P		BMDC	Note 2,3,4,5
Intraoperative Abdominal										
Intraoperative Neurological									5450	N-4- 0.2.4.5
Pediatric	<u> </u>	Р	Р	P	<u> </u>	Р	P		BMDC	Note 2,3,4,5
Small Organ				<u> </u>	ļ				<del>   </del>	
Neonatal Cephalic	<u> </u>		<u>L</u>		<u> </u>				<u> </u>	
Adult Cephalic	<u> </u>	<u>L</u> .	<u>.                                    </u>						<u> </u>	
Cardiac		<u> </u>	<u> </u>		<u> </u>		<u> </u>			
Trans-esophageal		<u> </u>	_		ļ					
Transrectal			ļ	<u> </u>	ļ					
Transvaginal		<u> </u>	<u> </u>				ļ	<u> </u>	<del>                                     </del>	
Transurethral		1	1	<u> </u>	ļ	ļ			<del>                                     </del>	
Intravascular	<u> </u>	<u> </u>			<u> </u>		1	ļ	+	11.0045
Peripheral vessel	<u> </u>	Р	Р	P	ļ	Р	Р		BMDC	Note 2,3,4,5
Laparoscopic			1							
Musculo-skeletal Conventional			<u> </u>							
Musculo-skeletal Superficial										- <del></del>
Other (specify)		1			<u> </u>			<u> </u>	<u></u>	<del></del>

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

Note 2 Ensemble tissue harmonic imagi
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Prescription Use (Per 21 CFR 801.109)

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

and Radiological Devices

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

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

Note 5 Power SieScape panoramic imaging

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:

						M	ode of Opera	ation		
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic									<u> </u>	
Fetal				<u> </u>					D1100	Note 2 2 4 6
Abdominal		Р	Р	<u>P</u> _		Р	Р		BMDC	Note 2,3,4,5
Intraoperative Abdominal				<u></u>	ļ					
Intraoperative Neurological				ļ					BMDC	Note 2,3,4,5
Pediatric		P	Р	P	ļ	P	Р		BIVIDO	
Small Organ (Note 1)		Р	Р	P		Р	Р		BMDC	Note 2,3,4,5
Neonatal Cephalic	1	Р	Р	Р		Р	Р		BMDC	Note 2,3,4,5
Adult Cephalic	<b>T</b>		Ī							
Cardiac	1.	E	Ε	_ E		E	E		BMDC	Note 2,3,4,5
Transesophageal					ļ		ļ——		<del> </del>	
Transrectal		Ţ	<u>l</u>							
Transvaginal					ļ	ļ	1		<del>                                     </del>	
Transurethral				1	ļ	ļ	ļ		-	
Intravascular	<u> </u>		↓		ļ			ļ		
Peripheral vessel	<u> </u>	]			ļ					
Laparoscopic		<u> </u>	<u> </u>		ļ	ļ				
Musculo-skeletal Conventional		Р	Р	Р		Р	Р	-	BMDC	Note 2,3,4,5
Musculo-skeletal Superficial		E	E	E		E	E		BMDC	Note 2,3,4,5
Other (specify)			-		1			<u> </u>		

N = new indication; P = previously cleared by FDA; 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

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:

	Mode of Operation									
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Ь	Р	Р	Р	Р	P		BMDC	Note 2,3,4,5
Abdominal		P	Р	Р	Р	Р	Р		BMDC	Note 2,3,4,5
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		Р	Р	P	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								_		
Adult Cephalic										
Cardiac										
Transesophageal									<u> </u>	
Transrectal										
Transvaginal									<u> </u>	
Transurethral									<u> </u>	
Intravascular									<u> </u>	
Peripheral vessel		Р	Р	Р	Р	P	Р		BMDC	Note 2,3,4,5
Laparoscopic									<u> </u>	
Musculo-skeletal Conventional		E	Ε	E	Е	Ε	E		вмос	Note 2,3,4,5
Musculo-skeletal Superficial		Е	E	E	Е	E	Ε		вмос	Note 2,3,4,5
Other (specify)		i								

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

Alaka 1	For example: breast	toctoc	thuroid	nonic	proctate	otc.
Note 1	For example, preasi-	testes.	trivioia.	penis.	prostate.	eic.

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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

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:

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

Intended Use:

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

	Mode of Operation									
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		Р	Р	Р	Р	Р	Р	~**	BMDC	Note 2,3,4,5
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric					ļ		ļ		1	
Small Organ (Note 1)		Р	P	Р	Р	Р	Р		BMDC	Note 2,3,4,5
Neonatal Cephalic		]	Ī							
Adult Cephalic		<u> </u>		<u> </u>						
Cardiac				<u></u>	ļ					
Transesophageal			<u> </u>						ļ	
Transrectal									ļ	
Transvaginal									<u> </u>	
Transurethral				<u>]                                    </u>			ļ			<del></del>
Intravascular								ļ		
Peripheral vessel		Р	P	P	Р	Р	P		BMDC	Note 2,3,4,5
Laparoscopic				<u> </u>			<u> </u>		<b> </b>  _	
Musculo-skeletal Conventional		Р	P	Р	Р	Р	Р		ВМОС	Note 2,3,4,5
Musculo-skeletal Superficial										
Other (specify)								<u> </u>	1	

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

Al-A- 4	For example: breas	tactor thyroid	nenis	prostate	eto
Note 1	For example, preas	r. testes, trivitoid.	, pems.	piusiale	, ew.

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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 \_\_\_\_\_K

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:

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:

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

N = new indication; P = previously cleared by FDA; 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)

Division of Reproductive, Abdominal,

and Radiological Devices

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:

		Mode of Operation										
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic												
Fetal	-	Р	Р	P		Ρ	P		BMDC	Note 4,5		
Abdominal		Р	P.	Р		Р	P .		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; 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, Abdominat,

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:

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

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

Note 1	For example:	breast, te	estes, th	yroid, peni	is, 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

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:

	Mode of Operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)			
Ophthalmic													
Fetal				<u> </u>					ļ				
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	P	Р		BMDC	Note 3,4,5			
Neonatal Cephalic				I									
Adult Cephalic													
Cardiac			ļ <u>.</u>						<b></b>				
Transesophageal													
Transrectal													
Transvaginal				<u> </u>									
Transurethral			ļ										
Intravascular	L												
Peripheral vessel		Р	Р	Р	Р	P	Р.		BMDC	Note 3,4,5			
Laparoscopic				ļ <u> </u>					1				
Musculo-skeletal Conventional		Р	Р	Р	Р	Р	Р		BMDC	Note 3,4,5			
Musculo-skeletal Superficial		Р	Р	Р	Р	Р	Р		вмос	Note 3,4,5			
Other (specify)									<u> </u>				

N = new indication; P = previously cleared by FDA; 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)

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Division of Reproductive, Abdominal,

and Radiological Devices

510(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:

						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				Ì						
Abdominal										
Intraoperative (note 6)		Р	Р	Р		Р	P		BMDC	Note 3
Intraoperative Neurological		Р	Р	Р		Р	Р		вмос	Note 3
Pediatric		Р	Р	Р		P	Р		BMDC	Note 3
Small Organ (Note 1)		P	Р	Р		P	Р		BMDC	Note 3
Neonatal Cephalic										
Adult Cephalic		<u> </u>							<u> </u>	
Cardiac										
Transesophagea!										
Transrectal										
Transvaginal										
Transurethral										
Intravascular			<u> </u>			:				
Peripheral vessel		Р	Р	Р		Р	Р		BMDC	Note 3
Laparoscopic										
Musculo-skeletal Conventional		Р	Р	Ρ		Р	Р		BMDC	Note 3
Musculo-skeletal Superficial		Р	Р	Р		Р	Р		BMDC	Note 3
Other (specify)										

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

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

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 Sign<sup>l</sup>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:

						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										***************************************
Abdominal		Р	Р	Ρ		P	Р		BMDC	Note 3,4,5
Intraoperative (Note 6)		Р	Р	Р		Р	Р		BMDC	Note 3,4,5
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		Р	Р	₽		Р	Р		BMDC	Note 3,4,5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		Р	₽	P		P	Р		BMDC	Note 3,4,5
Laparoscopic										
Musculo-skeletal Conventional		P	Р	Р		Р	P		вмос	Note 3,4,5
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; 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

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:

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

N = new indication; P = previously cleared by FDA; 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 Note 6 For example: abdominal, vascular

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> > Prescription Use (Per 21 CFR 801.109)

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

and To lambourgest Devices

5 Mic Sumber

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:

						Mo	de of Opera	ition		
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	Р	Р		Р	Р		BMDC	Note 3,4,5
Intraoperative Neurological										
Pediatric										
Small Organ							i			
Neonatal Cephalic	3									7
Adult Cephalic										
Cardiac										- 1
Transesophagea!								•		
Transrectal										
Transvaginal										
Transurethral								1		
Intravascular										
Peripheral vessel										
Laparoscopic		P	P	Р		Р	Р		BMDC	Note 3,4,5
Musculo-skeletal Conventional										
Musculo-skeletal Superficial						-				*** *** · · ·
Other (specify)										

N = new indication; P = previously cleared by FDA; 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, Abdominat.

and Radiological Devices

510(k) Number <u>K042042</u>

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:

				- V. 15 - III		Mo	de of Opera	ıtion		
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		Р	Р	Р	Р	Ρ.	Р		BMDC	Note 2,3
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ								_		
Neonatal Cephalic										
Adult Cephalic		Р	Р	P	Р	Р	P		BMDC	Note 2,3
Cardiac		Р	P	Р	Р	Р	Р		BMDC	Note 2,3,7
Transesophageal								<u>-</u>		
Transrectal				İ						
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic	,					-				
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; 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,

and Radiological Devices

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:

		Mode of Operation											
Clinical Application	4	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)			
Ophthalmic													
Fetal		Р	Р	P	Р	Р	Р		BMDC	Note 2			
Abdominal		Р	Р	P	P	Р	Р		BMDC	Note 2			
Intraoperative Abdominal										·			
Intraoperative Neurological							:						
Pediatric		Ρ	Р	P	P	P	Р		BMDC	Note 2			
Small Organ													
Neonatal Cephalic		₽	Р	P	Р	Р	Р		BMDC	Note 2			
Adult Cephalic													
Cardiac		P	P	₽	P	P	Р		BMDC	Note 2,7			
Transesophageal													
Transrectal													
Transvaginal													
Transurethral													
Intravascular													
Peripheral vessel													
Laparoscopic													
Musculo-skeletal Conventional													
Musculo-skeletal Superficial	•												
Other (specify)									<u> </u>				

N = new indication; P = previously cleared by FDA; 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, Abdomination

and Radiological 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	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic									<u> </u>	
Fetal										
Abdominal									<u> </u>	
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric							ļ <u></u>			
Small Organ (Specify)										
Neonatal Cephalic		<u> </u>								
Adult Cephalic			<u> </u>							
Cardiac	<u> </u>		<u> </u>							
Trans-esophageal		Р	P	Р	Р	P	Р		BMDC	Note 2,3
Transrectal			<u> </u>							
Transvaginal										
Transurethral			<u> </u>							
Intravascular				ļ						
Peripheral vessel						·				
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Note 2 Ensemble tissue harmonic imaging

Note 3 3D imaging

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> > Prescription Use (Per 21 CFR 801.109)

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

and Radiological Devices

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:

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

N = new indication; P = previously cleared by FDA; 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, Abdominat.

and Radiological Devices

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:

Clinical Application	Mode of Operation											
	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic								-				
Fetal												
Abdominal												
Intraoperative Abdominal												
Intraoperative Neurological								· · · · · · · · · · · · · · · · · · ·				
Pediatric									<u> </u>			
Small Organ												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Trans-esophageal				Ì	i							
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral vessel					Р							
Laparoscopic												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other (specify)												

N = new indication; P = previously cleared by FDA; 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 Sigh-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number (if known):

Device Name:

P9-4 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										
Fetal		N	N	N	N	N	N		BMDC	Note 2
Abdominal		N	N	N	N	N	N		BMDC	Note 2
Intraoperative Abdominal										
Intraoperative Neurological		N	N	N		Ν	N		BMDC	Note 2
Pediatric		N	N	N	N	N	N		BMDC	Note 2
Small Organ										
Neonatal Cephalic		N	N	N	N	N	N		BMDC	Note 2
Adult Cephalic										·
Cardiac		N	N	N	N	N	N		BMDC	Note 2,7
Transesophageal										
Transrectal										
Transvaginal								,		
Transurethral										
Intravascular										
Peripheral vessel		N	N	N	N	N	N		BMDC	Note 2
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial							-			
Other (specify)				-						

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

Note 2 Ensemble tissue harmonic 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,

and Radiological Devices

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