October 15, 2020



Siemens Medical Solutions, USA, Inc. % Ms. Christine Dunbar Senior Regulatory Affairs Specialist 22010 South East 51<sup>st</sup> Street ISSAQUAH WA 98029

## Re: K202683

Trade/Device Name: ACUSON Sequoia Diagnostic Ultrasound System, ACUSON SC2000 Diagnostic Ultrasound System, ACUSON Freestyle Diagnostic Ultrasound System, ACUSON S1000, S2000, S3000 Diagnostic Ultrasound Systems, ACUSON P200 Diagnostic Ultrasound System, ACUSON NX3, NX3 Elite Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, OBJ, LLZ, OIJ
Dated: September 11, 2020
Received: September 15, 2020

Dear Ms. Dunbar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm</a> identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <a href="https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products">https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products</a>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or gurrent good manufacturing practices (21 CFR 4, Subpart 4) for

regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <u>https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems</u>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<u>https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance</u>) and CDRH Learn (<u>https://www.fda.gov/training-and-continuing-education/cdrh-learn</u>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<u>https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice</u>) for more information or contact DICE by email (<u>DICE@fda.hhs.gov</u>) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.DirectorDivision of Radiological HealthOHT7: Office of In Vitro Diagnostics and Radiological HealthOffice of Product Evaluation and QualityCenter for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number *(if known)* K202683

Device Name

ACUSON Sequoia Diagnostic Ultrasound System

#### Indications for Use (Describe)

The ACUSON Sequoia ultrasound imaging system is intended to provide images of, or signals from, inside the body by an appropriately trained healthcare professional in a clinical setting for the following applications: Fetal, Abdominal, Pediatric, Neonatal Cephalic, Small Parts, OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures), Cardiac, Pelvic, Vascular, Adult Cephalic, Musculoskeletal and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures for fetal, abdominal, pediatric, small organ, cardiac, transrectal, transvaginal, peripheral vessel, musculoskeletal and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

#### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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FORM FDA 3881 (7/17)

510 (k) Number (if known):

Device Name:

Intended Use:

ACUSON Sequoia Diagnostic Ultrasound System Ultrasound imaging or fluid flow analysis of the human body as follows:

							Mode of Op	peration		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Р	Р		Р	Р		BMDC	
Abdominal		Р	Р	Р		Р	Р		BMDC	
Intraoperative										
Intraoperative Neurological										
Pediatric		Р	Р	Р	Р	Р	Р		BMDC	
Small Organ (Note 1)		Р	Р	Р		Р	Р		BMDC	
Neonatal Cephalic		Р	Р	Р		Р	Р		BMDC	
Adult Cephalic		Р	Р	Р		Р	Р		BMDC	
Cardiac		Р	Р	Р	Р	Р	Р		BMDC	
Trans-esophageal										
Transrectal		Р	Р	Р		Р	Р		BMDC	
Transvaginal		Р	Р	Р		Р	Р		BMDC	Volume Imaging
Transurethral										
Intravascular										
Peripheral vessel		Р	Р	Р		Р	Р		BMDC	
Laparoscopic										
Musculo-skeletal Conventional		Р	Р	Р		Ρ	Р		BMDC	
Musculo-skeletal Superficial		Р	Ρ	Р		Ρ	Р		BMDC	
Other (specify)										

N = new indication; P = previously cleared by K200707

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name: Intended Use:	<b>4V1 Phased Array Transducer</b> Ultrasound imaging or fluid flow analysis of the human body as follows:									ollows:
						M	ode of Operation	ation		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Р	Р		Р	Р		BMDC	
Abdominal		Р	Р	Р		Р	Р		BMDC	
Intraoperative										
Intraoperative Neurological										
Pediatric		Р	Р	Р		Р	Р		BMDC	
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name: Intended Use:	DAX Curved Array Transducer Ultrasound 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										
Fetal		Р	Р	Р		Р	Р		BMCD	
Abdominal		Р	Р	Р		Р	Р		BMCD	
Intraoperative										
Intraoperative Neurological										
Pediatric		Р	Р	Р		Р	Р		BMCD	
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name:

## 5C1 Curved Array Transducer

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

		Mode of Operation										
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic												
Fetal		Р	Р	Р		Р	Р		BMCD			
Abdominal		Р	Р	Р		Р	Р		BMCD			
Intraoperative												
Intraoperative Neurological												
Pediatric		Р	Р	Р		Р	Р		BMCD			
Small Organ (Note 1)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Trans-esophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral vessel												
Laparoscopic												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other (specify)												

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name:	9C3 Curved Array Transducer
Intended Use:	Ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
						IVIC			1 1	
Clinical Application	A	В	Μ	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Р	Р		Р	Р		BMCD	
Abdominal		Р	Р	Р		Р	Р		BMCD	
Intraoperative										
Intraoperative Neurological										
Pediatric		Р	Р	Р		Р	Р		BMCD	
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional		Ρ	Ρ	Ρ		Р	Р		BMCD	
Musculo-skeletal Superficial										
Other (specify)				-						

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name: Intended Use:														
		Mode of Operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)				
Ophthalmic														
Fetal														
Abdominal														
Intraoperative														
Intraoperative Neurological														
Pediatric		Р	Р	Р		Р	Р		BMCD					
Small Organ (Note 1)		Р	Ρ	Р		Ρ	Р		BMCD					
Neonatal Cephalic														
Adult Cephalic														
Cardiac														
Trans-esophageal														
Transrectal														
Transvaginal														
Transurethral														
Intravascular														
Peripheral vessel														
Laparoscopic														
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		BMCD					
Musculo-skeletal Superficial		Ρ	Ρ	Ρ		Ρ	Р		BMCD					
Other (specify)														

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name: Intended Use:		1 L	4L5 L Jltraso	<b>-inear</b> <i>I</i> bund im	Array T aging o	ransducer	analysis of	the huma	n body as fo	bllows:				
		Mode of Operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)				
Ophthalmic														
Fetal														
Abdominal														
Intraoperative														
Intraoperative Neurological														
Pediatric		Р	Р	Р		Р	Р		BMCD					
Small Organ (Note 1)		Р	Р	Р		Р	Р		BMCD					
Neonatal Cephalic														
Adult Cephalic														
Cardiac														
Trans-esophageal														
Transrectal														
Transvaginal														
Transurethral														
Intravascular														
Peripheral vessel		Р	Р	Р		Р	Р		BMCD					
Laparoscopic														
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		BMCD					
Musculo-skeletal Superficial		Р	Р	Р		Ρ	Р		BMCD					
Other (specify)														

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name: Intended Use:	<b>10L4 Linear Array Transducer</b> Ultrasound imaging or fluid flow analysis of the human body as follows:									llows:
						M	ode of Opera	ation		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Р	Р	Р		Р	Р		BMCD	
Abdominal		Р	Р	Р		Р	Р		BMCD	
Intraoperative										
Intraoperative Neurological										
Pediatric		Р	Р	Р		Р	Р		BMCD	
Small Organ (Note 1)		Р	Ρ	Р		Ρ	Р		BMCD	
Neonatal Cephalic		Р	Р	Р		Р	Р		BMCD	
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		Р	Р	Р		Р	Р		BMCD	
Laparoscopic										
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		BMCD	
Musculo-skeletal Superficial		Р	Р	Р		Р	Р		BMCD	
Other (specify)										

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name: Intended Use:

#### **9EC4 Endocavity Transducer** Ultrasound 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										
Fetal										
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal		Р	Р	Р		Р	Р		BMCD	
Transvaginal		Р	Р	Р		Р	Р		BMCD	
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name: Intended Use:		<b>5V1 Phased Array Transducer</b> Ultrasound 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													
Fetal													
Abdominal													
Intraoperative													
Intraoperative Neurological													
Pediatric		Р	Р	Р	Р	Р	Р		BMCD				
Small Organ (Note 1)													
Neonatal Cephalic													
Adult Cephalic		Р	Р	Р		Р	Р		BMCD				
Cardiac		Р	Р	Р	Р	Р	Р		BMCD				
Trans-esophageal													
Transrectal													
Transvaginal													
Transurethral													
Intravascular													
Peripheral vessel													
Laparoscopic													
Musculo-skeletal Conventional													
Musculo-skeletal Superficial													
Other (specify)													

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name: Intended Use:	8V3 Phased Array Transducer Ultrasound imaging or fluid flow analysis of the human body as follows:									llows:
						M	ode of Opera	ation		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		Р	Р	Р		Р	Р		BMCD	
Intraoperative										
Intraoperative Neurological										
Pediatric		Р	Р	Р	Р	Р	Р		BMCD	
Small Organ (Note 1)										
Neonatal Cephalic		Р	Р	Р		Р	Р		BMCD	
Adult Cephalic										
Cardiac		Р	Р	Р	Р	Р	Р		BMCD	
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name: Intended Use:	CW2 Continuous Wave Transducer Ultrasound 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										
Fetal										
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric					Р					
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					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 K200707

Additional Comments:

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name: Intended Use:		<b>10V4 Phased Array Transducer</b> Ultrasound 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													
Fetal													
Abdominal													
Intraoperative													
Intraoperative Neurological													
Pediatric		Р	Р	Р	Р	Р	Р		BMCD				
Small Organ (Note 1)													
Neonatal Cephalic		Р	Р	Р		Р	Р		BMCD				
Adult Cephalic													
Cardiac		Р	Р	Р	Р	Р	Р		BMCD				
Trans-esophageal													
Transrectal													
Transvaginal													
Transurethral													
Intravascular													
Peripheral vessel													
Laparoscopic													
Musculo-skeletal Conventional													
Musculo-skeletal Superficial													
Other (specify)													

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name: Intended Use:		1 L	<b>8H6</b> I Jltraso	L <b>inear</b> A	Array T aging o	ransduce	r analysis of	the huma	n body as fo	ollows:			
		Mode of Operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)			
Ophthalmic													
Fetal													
Abdominal													
Intraoperative													
Intraoperative Neurological													
Pediatric													
Small Organ (Note 1)		Р	Р	Р		Р	Р		BMCD				
Neonatal Cephalic													
Adult Cephalic													
Cardiac													
Trans-esophageal													
Transrectal													
Transvaginal													
Transurethral													
Intravascular													
Peripheral vessel													
Laparoscopic													
Musculo-skeletal Conventional													
Musculo-skeletal Superficial		Р	Р	Р		Р	Р		BMCD				
Other (specify)													

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name: Intended Use:		<b>CW5 Continuous Wave Transducer</b> Ultrasound 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											
Fetal											
Abdominal											
Intraoperative											
Intraoperative Neurological											
Pediatric											
Small Organ (Note 1)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel					Р						
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

#### 510 (k) Number (if known):

Device Name:	7L2 Linear Array Transducer										
Intended Use:		U	Iltrasc	ound im	aging o	r fluid flow	analysis of	the humai	n body as fo	ollows:	
						Mo	ode of Opera	ation			
Clinical Application	A	В	Μ	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic											
Fetal											
Abdominal		Р	Р	Р		Р	Р		BMCD		
Intraoperative											
Intraoperative Neurological											
Pediatric		Р	Р	Р		Р	Р		BMCD		
Small Organ (Note 1)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		Р	Р	Р		Р	Р		BMCD		
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name: Intended Use:	<b>11M3 Curved Array Transducer</b> Ultrasound 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										
Fetal										
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric		Р	Р	Р		Р	Р		BMCD	
Small Organ (Note 1)										
Neonatal Cephalic		Р	Р	Р		Р	Р		BMCD	
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

# Device Name: 9VE4 Curved Endovaginal Mechanical 3D Transducer Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows: Mode of Operation

		Mode of Operation										
Clinical Application	A	В	Μ	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic												
Fetal												
Abdominal												
Intraoperative												
Intraoperative Neurological												
Pediatric												
Small Organ (Note 1)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Trans-esophageal												
Transrectal												
Transvaginal		Ν	Ν	Ν		Ν	N		BMCD	Volume Imaging		
Transurethral												
Intravascular												
Peripheral vessel												
Laparoscopic												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other (specify)												

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

## Indications for Use

510(k) Number *(if known)* K202683

#### Device Name

ACUSON SC2000 Diagnostic Ultrasound System

#### Indications for Use (Describe)

The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transesophageal, Adult Cephalic, Peripheral Vessel, Abdominal, Intraoperative Abdominal, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications. The system also provides the ability to measure anatomical structures and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

The typical examinations performed using the SC2000 Ultrasound System are:

Cardiac Imaging Applications and Analysis

The system transmits ultrasound energy into adult, pediatric, neonatal, and fetal cardiac patients creating 2D (B), 3D, MMode (M), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave (PW) Doppler, and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the heai1, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system also supports catheters which are intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures. The system has Cardiac Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes. Vascular Imaging Applications and Analysis

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the carotid arteries or juggler veins in the neck; superficial and deep veins and arteries in the arms and legs and abdomen; and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images. The system has Vascular Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes. Superficial Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of conventional or superficial musculoskeletal structures and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

Intraoperative Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), and Pulsed Wave Doppler (PWD) to obtain images and blood flow velocity that provide guidance during intraoperative procedures.

**Transcranial Imaging Applications** 

The system transmits ultrasound energy into the cranium of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the brain and surrounding anatomical structures to evaluate the presence or absence of pathology. The system provides Measurement Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

X Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

#### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff *PRAStaff@fda.hhs.gov* 

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

## Indications for Use

510(k) Number *(if known)* K202683

Device Name

ACUSON Freestyle Diagnostic Ultrasound System

Indications for Use (Describe)

The ACUSON Freestyle Ultrasound System is intended for diagnostic imaging or fluid flow analysis of the human body performed by an appropriately trained healthcare professional in a healthcare setting for the following conditions: Abdominal, Pediatric, Small Organ, Peripheral Vessel, Musculoskeletal (Conventional), Musculoskeletal (Superficial).

Type of Use	(Select one or both, as applicable)	

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff *PRAStaff@fda.hhs.gov* 

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Form Approved: OMB No. 0910-0120 Expiration Date: 06/30/2020 See PRA Statement below

510 (k) Number (if known):

Device Name:

Intended Use:

ACUSON Freestyle<sup>TM</sup> Diagnostic Ultrasound System 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	Combined (Specify) (Note 2)	Other (Specify)			
Ophthalmic													
Fetal													
Abdominal		Р				Р	Р						
Intraoperative Intraoperative Neurological													
Pediatric		Р				Р	Р						
Small Organ (Note 1)		Р				Р	Р						
Neonatal Cephalic													
Adult Cephalic													
Cardiac													
Trans-esophageal													
Transrectal													
Transvaginal													
Transurethral													
Intravascular													
Peripheral vessel		Р				Р	Р						
Laparoscopic													
Musculo-skeletal Conventional		Р	Р	Р		Р	Р						
Musculo-skeletal Superficial		Р	Р	Р		Р	Р						
Other (specify)													

N = new indication; P = previously cleared by K162417, Blank = Not Claimed

 Additional Comments:

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

 Note 2
 B-mode and PWD mode or Color Doppler and PW mode

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name: Intended Use:	L8-3 Linear Array Transducer 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) (Note 2)	Other (Specify)	
Ophthalmic											
Fetal											
Abdominal		Р				Р	Р				
Intraoperative											
Intraoperative Neurological											
Pediatric		Р				Р	Р				
Small Organ (Note 1)		Р				Р	Р				
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		Р				Р	Р				
Laparoscopic											
Musculo-skeletal Conventional		Р				Ρ	Р				
Musculo-skeletal Superficial		Р				Р	Р				
Other (specify)											

N = new indication; P = previously cleared by K162417, Blank = Not Claimed

Additional Comments:

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

 Note 2
 B-mode and PWD mode or Color Doppler and PW mode

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name: Intended Use:	L13-5 Linear Array Transducer 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) (Note 2)	Other (Specify)				
Ophthalmic														
Fetal														
Abdominal		Р				Р	Р							
Intraoperative														
Intraoperative Neurological														
Pediatric		Р				Р	Р							
Small Organ (Note 1)		Р				Р	Р							
Neonatal Cephalic														
Adult Cephalic														
Cardiac														
Trans-esophageal														
Transrectal														
Transvaginal														
Transurethral														
Intravascular														
Peripheral vessel		Р				Р	Р							
Laparoscopic														
Musculo-skeletal Conventional		Ρ				Ρ	Р							
Musculo-skeletal Superficial		Р				Ρ	Р							
Other (specify)														

N = new indication; P = previously cleared by K162417, Blank = Not Claimed

Additional Comments:

Note 1 Note 2

For example: breast, testes, thyroid, penis etc. B-mode and PWD mode or Color Doppler and PW mode

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off - Office of In Vitro Diagnostic Devices 510(k)\_\_\_\_

Page 3 of 5

510 (k) Number (if known):

Device Name: Intended Use:	L17-5 Linear Array Transducer 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) (Note 2)	Other (Specify)				
Ophthalmic														
Fetal														
Abdominal		Ν				N	N							
Intraoperative Intraoperative Neurological														
Pediatric		N				N	N							
Small Organ (Note 1)		N				N	N							
Neonatal Cephalic														
Adult Cephalic														
Cardiac														
Trans-esophageal														
Transrectal														
Transvaginal														
Transurethral														
Intravascular														
Peripheral vessel		Ν				Ν	Ν							
Laparoscopic														
Musculo-skeletal Conventional		N				N	N							
Musculo-skeletal Superficial		Ν				N	N							
Other (specify)														

N = new indication; P = previously cleared by K162417, Blank = Not Claimed

Additional Comments:

Note 1 Note 2

For example: breast, testes, thyroid, penis etc. B-mode and PWD mode or Color Doppler and PW mode

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name: Intended Use:		<b>C5-2 Curvilinear Array Transducer</b> Diagnostic 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) (Note 2)	Other (Specify)				
Ophthalmic														
Fetal														
Abdominal		Р				Р	Р							
Intraoperative														
Intraoperative Neurological														
Pediatric	1	Р				Р	Р							
Small Organ (Note 1)		Р				Р	Р							
Neonatal Cephalic														
Adult Cephalic														
Cardiac														
Trans-esophageal														
Transrectal														
Transvaginal														
Transurethral														
Intravascular														
Peripheral vessel		Р				Р	Р							
Laparoscopic														
Musculo-skeletal Conventional		Р				Р	Р							
Musculo-skeletal Superficial		Р				Р	Р							
Other (specify)														

N = new indication; P = previously cleared by K162417, Blank = Not Claimed

Additional Comments:

Note 1 Note 2 For example: breast, testes, thyroid, penis etc. B-mode and PWD mode or Color Doppler and PW mode

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

## Indications for Use

510(k) Number (if known)

### K202683

#### Device Name

S1000, S2000, S3000 Diagnostic Ultrasound Systems

#### Indications for Use (Describe)

The ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN (including monitoring of the ovarian follicle development), Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures {fetal, abdominal, intraoperative, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, trans-esophageal, transrectal, transvaginal, peripheral vessel, musculo-skeletal (conventional), musculo-skeletal (superficial) and neonatal cardiac} and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

The ACUSON AcuNav Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.

Transducer Indications for Use are on the attached pages.

Type of Use (Select one or both, as applicable)	
Prescription Use (Part 21 CFR 801 Subpart D)	Over-The-Counter Use (21 CFR 801 Subpart C)
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510 (k) Number (if known): Device Name: Intended Use:

ACUSON S1000, S2000 and S3000 Ultrasound Systems Ultrasound imaging or fluid flow analysis of the human body as follows:

		Mode of Operation									
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic											
Fetal		Ρ	Р	Р	Р	Р	Р		BMDC		
Abdominal		Ρ	Ρ	Р	Р	Р	Р		BMDC		
Intraoperative		Р	Ρ	Ρ	Р	Р	Р		BMDC	Note 2	
Intraoperative Neurological											
Pediatric		Р	Р	Р	Р	Р	Р		BMDC		
Small Organ		Р	Ρ	Ρ	Р	Р	Р		BMDC	Note 1	
Neonatal Cephalic		Р	Р	Р	Р	Р	Р		BMDC		
Adult Cephalic		Р	Р	Р	Р	Р	Р		BMDC		
Cardiac		Р	Р	Р	Р	Р	Р		BMDC		
Trans-esophageal		Р	Р	Р	Р	Р	Р		BMDC		
Transrectal		Р	Ρ	Р		Р	Р		BMDC		
Transvaginal		Р	Ρ	Р		Р	Р		BMDC		
Transurethral											
Intravascular											
Peripheral vessel		Р	Р	Р	Р	Р	Р		BMDC		
Laparoscopic											
Musculo-skeletal Conventional		Ρ	Р	Р	Р	Р	Ρ		BMDC		
Musculo-skeletal Superficial		Р	Р	Р	Р	Р	Р		BMDC		
Other (specify) Neonatal Cardiac		Ρ	Р	Р	Р	Р	Р		BMDC		

N = new indication; P = previously cleared by FDA K162243

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc. Note 2 For example: vascular, abdominal

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

510 (k) Number (if known): Device Name:

# 12L4 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

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

		Mode of Operation								
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric		Р	Ρ	Ρ		Р	Р		BMDC	
Small Organ			Ρ	Р		Р	Р		BMDC	Note 1
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		Ρ	Ρ	Р		Р	Р		BMDC	
Laparoscopic										
Musculo-skeletal Conventional		Ρ	Р	Р		Р	Р		BMDC	
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K162243

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc. Note 2 For example: vascular, abdominal

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

510 (k) Number (if known): Device Name:

#### CW2 Probe for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

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

		Mode of Operation								
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal					Р					
Abdominal					Р					
Intraoperative					Р					Note 2
Intraoperative Neurological										
Pediatric					Р					
Small Organ					Р					Note 1
Neonatal Cephalic					Р					
Adult Cephalic					Р					
Cardiac					Р					
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel					Р					
Laparoscopic										
Musculo-skeletal Conventional					Ρ					
Musculo-skeletal Superficial					Р					
Other (specify)										

N = new indication; P = previously cleared by FDA K162243

Additional Comments:

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

Note 2 For example: vascular, abdominal

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

510 (k) Number (if known): Device Name:

#### CW5 Probe for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

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

		Mode of Operation								
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal					Р					
Abdominal					Р					
Intraoperative					Р					Note 2
Intraoperative Neurological					Р					
Pediatric					Ρ					
Small Organ					Р					Note 1
Neonatal Cephalic					Ρ					
Adult Cephalic					Р					
Cardiac					Ρ					
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel					Р					
Laparoscopic										
Musculo-skeletal Conventional					Р					
Musculo-skeletal Superficial					Р					
Other (specify)										

N = new indication; P = previously cleared by FDA K162243

Additional Comments:

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

Note 2 For example: vascular, abdominal

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

510 (k) Number (if known): Device Name:

## EC9-4 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

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

		Mode of Operation								
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Ρ	Ρ	Р		Р	Р		BMDC	
Abdominal		Ρ	Ρ	Р		Р	Р		BMDC	
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ		Ρ	Ρ	Р		Р	Р		BMDC	Note 1
Neonatal Cephalic		Ρ	Ρ	Р		Р	Р		BMDC	
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal		Ρ	Ρ	Р		Р	Р		BMDC	
Transvaginal		Ρ	Ρ	Р		Р	Р		BMDC	
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K162243

Additional Comments:

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

Note 2 For example: vascular, abdominal

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

510 (k) Number (if known): Device Name:

# MC9-4 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

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

		Mode of Operation									
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic											
Fetal		Ρ	Ρ	Р		Р	Р		BMDC		
Abdominal		Ρ	Ρ	Р		Р	Р		BMDC		
Intraoperative											
Intraoperative Neurological											
Pediatric											
Small Organ		Р	Р	Р		Р	Р		BMDC	Note 1	
Neonatal Cephalic		Ρ	Ρ	Р		Р	Р		BMDC		
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal		Р	Ρ	Р		Р	Р		BMDC		
Transvaginal		Р	Ρ	Р		Р	Р		BMDC		
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA K162243

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc. Note 2 For example: vascular, abdominal

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

510 (k) Number (if known): Device Name:

# 9L4 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

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

						Mo	ode of Oper	ation		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Ρ	Ρ	Р		Р	Р		BMDC	
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric		Р	Р	Р		Р	Р		BMDC	
Small Organ		Ρ	Р	Р		Р	Р		BMDC	Note 1
Neonatal Cephalic		Ρ	Ρ	Р		Р	Р		BMDC	
Adult Cephalic		Ρ	Ρ	Р		Р	Р			
Cardiac		Ρ	Ρ	Р		Р	Р		BMDC	
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		Ρ	Ρ	Р		Р	Р		BMDC	
Laparoscopic										
Musculo-skeletal Conventional		Ρ	Р	Р		Р	Р		BMDC	
Musculo-skeletal Superficial		Ρ	Р	Ρ		Р	Р		BMDC	
Other (specify)										

N = new indication; P = previously cleared by FDA K162243

Additional Comments:

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

Note 2 For example: vascular, abdominal

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

510 (k) Number (if known): Device Name:

# 14L5 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

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

		Mode of Operation										
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic												
Fetal												
Abdominal												
Intraoperative												
Intraoperative Neurological												
Pediatric												
Small Organ		Ρ	Ρ	Р		Р	Ρ		BMDC	Note 1		
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Trans-esophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral vessel		Ρ	Ρ	Р		Р	Р		BMDC			
Laparoscopic												
Musculo-skeletal Conventional		Р	Р	Ρ		Р	Р		BMDC			
Musculo-skeletal Superficial												
Other (specify)												

N = new indication; P = previously cleared by FDA K162243

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc. Note 2 For example: vascular, abdominal

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

510 (k) Number (if known): Device Name:

# 4P1 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

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

		Mode of Operation										
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic												
Fetal		Р	Ρ	Р	Р	Р	Р		BMDC			
Abdominal		Ρ	Ρ	Р	Р	Р	Р		BMDC			
Intraoperative												
Intraoperative Neurological												
Pediatric												
Small Organ												
Neonatal Cephalic												
Adult Cephalic		Р	Ρ	Р	Р	Р	Р		BMDC			
Cardiac		Ρ	Ρ	Р	Р	Р	Р		BMDC			
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 K162243

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc. Note 2 For example: vascular, abdominal

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

510 (k) Number (if known):

Device Name:

#### 6C2 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

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

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

N = new indication; P = previously cleared by FDA K162243 Additional Comments:

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

Note 2 For example: vascular, abdominal

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

510 (k) Number (if known):

Device Name:

#### 4C1 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

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

		Mode of Operation										
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic												
Fetal		Ρ	Ρ	Р	Р	Ρ	Р		BMDC			
Abdominal		Ρ	Р	Р	Р	Ρ	Р		BMDC			
Intraoperative												
Intraoperative Neurological												
Pediatric												
Small Organ		Ρ	Р	Р	Р	Ρ	Р		BMDC	Note 2		
Neonatal Cephalic												
Adult Cephalic												
Cardiac		Ρ	Р	Ρ	Ρ	Ρ	Р		BMDC			
Trans-esophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral vessel		Р	Ρ	Р	Ρ	Р	Р		BMDC			
Laparoscopic												
Musculo-skeletal												
Conventional												
Musculo-skeletal Superficial												
Other (specify)												

N = new indication; P = previously cleared by FDA K162243

Additional Comments:

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

Note 2 For example: vascular, abdominal

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

510 (k) Number (if known): Device Name:

# 6C1 HD Transducer for use with ACUSON S2000 and S3000 Ultrasound Systems

Intended Use:

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

						Mo	de of Oper	ation		
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Ρ	Ρ	Р	Р	Р	Р		BMDC	
Abdominal		Ρ	Ρ	Р	Р	Р	Р		BMDC	
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ		Ρ	Ρ	Р	Р	Р	Р		BMDC	Note 2
Neonatal Cephalic										
Adult Cephalic										
Cardiac		Ρ	Ρ	Р	Р	Р	Р		BMDC	
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		Ρ	Ρ	Р	Ρ	Р	Р		BMDC	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K162243

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc. Note 2 For example: vascular, abdominal

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

510 (k) Number (if known):

Device Name:

8C3 HD Transducer for use with ACUSON S2000 and S3000 Ultrasound Systems

Intended Use:

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

		Mode of Operation									
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic											
Fetal		Ρ	Ρ	Р		Р	Р		BMDC		
Abdominal		Ρ	Ρ	Р		Р	Р		BMDC		
Intraoperative											
Intraoperative Neurological											
Pediatric		Ρ	Р	Ρ		Р	Р		BMDC		
Small Organ		Ρ	Ρ	Р		Р	Р		BMDC	Note 2	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel		Ρ	Ρ	Р		Р	Р		BMDC		
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N = new indication; P = previously cleared by FDA K162243

Additional Comments:

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

Note 2 For example: vascular, abdominal

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

510 (k) Number (if known):

Device Name:

#### 4V1 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

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

		Mode of Operation									
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)	
Ophthalmic											
Fetal		Ρ	Ρ	Р		Р	Р		BMDC		
Abdominal		Ρ	Ρ	Р		Р	Р		BMDC		
Intraoperative											
Intraoperative Neurological											
Pediatric											
Small Organ											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
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 K162243

Additional Comments:

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

Note 2 For example: vascular, abdominal

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

510 (k) Number (if known):

Device Name:

#### 10V4 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

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

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

N = new indication; P = previously cleared by FDA K162243

Additional Comments:

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

Note 2 For example: vascular, abdominal

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

510 (k) Number (if known):

Device Name:

14L5 SP Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Indications For Use:

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

						Мс	de of Oper	ation		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative		Р	Ρ	Р		Р	Р		BMDC	Note 2
Intraoperative Neurological										
Pediatric										
Small Organ		Р	Р	Р		Р	Р		BMDC	Note 1
Neonatal Cephalic										
Adult Cephalic										
Cardiac		Р	Р	Р		Р	Р		BMDC	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		Р	Р	Р		Р	Р		BMDC	
Laparoscopic										
Musculo-skeletal Conventional		Р	Р	Ρ		Р	Ρ		BMDC	
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K162243

Additional Comments:

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

Note 2 For example: vascular, abdominal

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

510 (k) Number (if known):

Device Name:

7CF2 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

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

						Мо	de of Opera	ation		
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Ρ	Ρ	Р		Р	Р		BMDC	
Abdominal		Ρ	Ρ	Р		Р	Р		BMDC	
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
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 K162243

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc. Note 2 For example: vascular, abdominal

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

510 (k) Number (if known):

Device Name:

#### 7CF1 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

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

		Mode of Operation										
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic												
Fetal		Ρ	Ρ	Р		Р	Р		BMDC			
Abdominal		Р	Ρ	Р		Р	Р		BMDC			
Intraoperative												
Intraoperative Neurological												
Pediatric												
Small Organ												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
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 K162243

Additional Comments:

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

Note 2 For example: vascular, abdominal

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

510 (k) Number (if known):

Device Name:

#### 9EVF4 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

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

						Мс	de of Oper	ation		
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Ρ	Ρ	Р		Р	Р		BMDC	
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic		Ρ	Ρ	Р		Р	Р		BMDC	
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal		Ρ	Ρ	Р		Р	Р		BMDC	
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K162243 Additional Comments:

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

Note 2 For example: vascular, abdominal

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

510 (k) Number (if known): Device Name:

# V5Ms Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

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

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

N = new indication; P = previously cleared by FDA K162243

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc. Note 2 For example: vascular, abdominal

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

510 (k) Number (if known): Device Name:

# 18L6 HD Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

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

		Mode of Operation										
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)		
Ophthalmic												
Fetal												
Abdominal												
Intraoperative												
Intraoperative Neurological												
Pediatric												
Small Organ		Ρ	Р	Р		Р	Р		BMDC	Note 1		
Neonatal Cephalic												
Adult Cephalic												
Cardiac		Ρ	Р	Р		Р	Р		BMDC			
Trans-esophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral vessel		Ρ	Ρ	Р		Р	Р		BMDC			
Laparoscopic												
Musculo-skeletal Conventional		Р	Р	Р		Р	Р		BMDC			
Musculo-skeletal Superficial		Р	Р	Р		Р	Р		BMDC			
Other (specify)												
- now indication:		-	laual		ا برما ام		0.40					

N = new indication; P = previously cleared by FDA K162243

Additional Comments:

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

Note 2 For example: vascular, abdominal

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510 (k) Number (if known): Device Name:

## 8V3 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

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

						Мс	de of Oper	ation		
Clinical Application	А	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Ρ	Ρ	Р	Р	Р	Р		BMDC	
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric		Ρ	Р	Р	Р	Р	Р		BMDC	
Small Organ										
Neonatal Cephalic		Ρ	Ρ	Ρ	Р	Р	Р		BMDC	
Adult Cephalic										
Cardiac		Р	Р	Р	Р	Р	Р		BMDC	
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify) Neonatal Cardiac		Ρ	Ρ	Р	Р	Р	Р		BMDC	

N = new indication; P = previously cleared by FDA K162243 Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc. Note 2 For example: vascular, abdominal

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

510 (k) Number (if known): Device Name:

## 4V1c Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

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

						Мс	de of Oper	ation		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Ρ	Ρ	Р	Р	Р	Р		BMDC	
Abdominal		Ρ	Ρ	Р	Р	Р	Р		BMDC	
Intraoperative		Ρ	Ρ	Р	Р	Р	Р		BMDC	Note 2
Intraoperative Neurological		Р	Р	Р	Р	Р	Ρ		BMDC	
Pediatric		Ρ	Ρ	Р	Р	Р	Р		BMDC	
Small Organ										
Neonatal Cephalic										
Adult Cephalic		Р	Р	Р	Р	Р	Р		BMDC	
Cardiac		Ρ	Р	Р	Р	Р	Р		BMDC	
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		Ρ	Ρ	Р	Р	Р	Р		BMDC	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify) Neonatal Cardiac		Ρ	Р	Р	Р	Р	Ρ		BMDC	

N = new indication; P = previously cleared by FDA K162243 Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc. Note 2 For example: vascular, abdominal

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510 (k) Number (if known): Device Name:

# EV-8C4 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

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

						Mo	ode of Oper	ation		
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		Ρ	Ρ	Р	Р	Р	Р		BMDC	
Abdominal		Ρ	Ρ	Р	Р	Р	Р		BMDC	
Intraoperative										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal		Ρ	Ρ	Р	Р	Р	Р		BMDC	
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)				1						

N = new indication; P = previously cleared by FDA K162243

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc. Note 2 For example: vascular, abdominal

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510 (k) Number (if known):

Device Name:

#### V7MTransducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

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

		Mode of Operation									
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify) *	Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal											
Abdominal		Р	Ρ	Р	Р	Р	Р		Р	Р	
Intraoperative											
Intraoperative Neurological											
Pediatric		Р	Ρ	Р	Р	Р	Р		Р	Р	
Small Organ											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		Ρ	Ρ	Р	Р	Р	Р		Р	Р	
Trans-esophageal		Р	Ρ	Р	Р	Р	Р		Р	Р	
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal											
(Conventional)											
Musculo-skeletal (Superficial)											
Other (specify)											

N = new indication; P = previously cleared by FDA K162243

Additional Comments:

\*Combinations include: <u>B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE</u>

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510 (k) Number (if known): Device Name:

# AcuNav 8F Ultrasound Catheter for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

The AcuNav<sup>TM</sup> Ultrasound Catheter is intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients.

	Γ					Mor	de of Operation			
Clinical Application						Color	Power	Color	Combined	Other:
	А	В	М	PWD	CWD	Doppler	(Amplitude)	Velocity	(Specify) *	Harmonic
							Doppler	Imaging		Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative										
(Vascular)										
Intraoperative										
(Neurological)										
Pediatric		Ρ	Р	Р	Р	Р	Р		Р	
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		Р	Р	Р	Р	Р	Р		Р	
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal		Р	Ρ	Р	Р	Р	Р		Р	
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal										
Superficial										
Other (Intra-Cardiac)		Ρ	Ρ	Р	Р	Р	Р		Р	

N = new indication; P = previously cleared by FDA K162243

Additional Comments:

\*Combinations include: <u>B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+PWD+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Dop</u>

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510 (k) Number (if known): Device Name:

# AcuNav 10F Ultrasound Catheter for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems

Intended Use:

The AcuNav<sup>™</sup> Ultrasound Catheter is intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients.

		Mode of Operation										
Clinical Application	A	в	М	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify) *	Other: Harmonic Imaging		
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Vascular)												
Intraoperative (Neurological)												
Pediatric		Ρ	Ρ	Р	Р	Р	Р		Р			
Small Organ												
Neonatal Cephalic												
Adult Cephalic												
Cardiac		Ρ	Ρ	Р	Р	Р	Р		Р			
Trans-esophageal												
Transrectal												
Transvaginal												
Transurethral												
Intra-Luminal		Ρ	Р	Р	Р	Р	Р		Р			
Peripheral Vessel												
Laparoscopic												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other (Intra-Cardiac)		Ρ	Ρ	Р	Р	Р	Р		Р			

 $\overline{N}$  = new indication; P = previously cleared by FDA K162243

Additional Comments:

\*Combinations include: <u>B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Colo Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler</u>

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# Indications for Use

510(k) Number (if known)

K202683

Device Name ACUSON P200 Diagnostic Ultrasound System

# Indications for Use (Describe)

The ACUSON P200 ultrasound imaging system is intended for the following applications: Fetal, Abdominal, Pediatric, Small Parts, OB/GYN (useful for visualization of the ovaries, follicles, uterus, and other pelvic structures), Adult, Pediatric and Neonatal Cardiac, Pelvic, Neonatal Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures; fetal, abdominal, pediatric, small organ, neonatal cephalic, cardiac (adult, pediatric and neonatal), trans-esophageal, transrectal, transvaginal, peripheral vessel, musculoskeletal (conventional), musculoskeletal (superficial) and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Type of Use (Select one or both, as ap	pplicable)
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Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff *PRAStaff@fda.hhs.gov* 

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510 (k) Number (if known):

Device Name:

### **ACUSON P200 Diagnostic Ultrasound System**

Intended Use:

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

		Mode of Operation										
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Specify)	Other (Specify)				
Ophthalmic												
Fetal	Р	Р	Р		Р	Р	BMDC					
Abdominal	Р	Р	Р		Р	Р	BMDC					
Intraoperative												
Intraoperative Neurological												
Pediatric	Р	Р	Р	Р	Р	Р	BMDC					
Small Organ (Note 1)	Р	Р	Р		Р	Р	BMCD					
Neonatal Cephalic	Р	Р	Р		Р	Р	BMCD					
Adult Cephalic												
Cardiac	Р	Р	Р	Р	Р	Р	BMCD					
Trans-esophageal	Р	Р	Р	Р	Р	Р	BMCD					
Transrectal	Р	Р	Р		Р	Р	BMCD					
Transvaginal	Р	Р	Р		Р	Р	BMCD					
Transurethral												
Intravascular												
Peripheral vessel (Note 2)	Ρ	Р	Р	Р	Р	Р	BMCD					
Laparoscopic												
Musculo-skeletal Conventional	Ρ	Р	Р		Р	Р	BMCD					
Musculo-skeletal Superficial	Ρ	Ρ	Р		Р	Р	BMCD					
Other (specify)												

N = new indication; P = previously cleared by FDA K180067; K180039; K187357

Note 1 Note 2 For example: Breast, Thyroid, Testis For example: Carotid, Arterial, Venous

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name: Intended Use:

### 4V1 Phased Array Transducer

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

		Mode of Operation										
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Specify)	Other (Specify)				
Ophthalmic												
Fetal	Р	Р	Р		Р	Р	BMDC					
Abdominal	Р	Р	Р		Р	Р	BMDC					
Intraoperative												
Intraoperative Neurological												
Pediatric	Р	Р	Р		Р	Р	BMDC					
Small Organ (Note 1)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Trans-esophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral vessel (Note 2)												
Laparoscopic												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other (specify)												

N = new indication; P = previously cleared by FDA K180067

 Note 1
 For example: Breast, Thyroid, Testis

 Note 2
 For example: Carotid, Arterial, Venous

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name:

Intended Use:

**5V1 Phased Array Transducer** Ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode of Ope	eration		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative								
Intraoperative Neurological								
Pediatric	Р	Р	Р	Р	Р	Р	BMCD	
Small Organ (Note 1)								
Neonatal Cephalic								
Adult Cephalic								
Cardiac	Р	Р	Р	Р	Р	Р	BMCD	
Trans-esophageal								
Transrectal								
Transvaginal								
Transurethral								
Intravascular								
Peripheral vessel (Note 2)								
Laparoscopic								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Other (specify)								

N = new indication; P = previously cleared by FDA K180067

Note 1 Note 2

For example: Breast, Thyroid, Testis For example: Carotid, Arterial, Venous

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name:

# 8V3 Phased Array Transducer

Intended Use:

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

					Mode of Ope	eration		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Fetal								
Abdominal	Р	Р	Р		Р	Р	BMCD	
Intraoperative								
Intraoperative Neurological								
Pediatric	Р	Р	Р	Р	Р	Р	BMCD	
Small Organ (Note 1)								
Neonatal Cephalic								
Adult Cephalic								
Cardiac	Р	Р	Р	Р	Р	Р	BMCD	
Trans-esophageal								
Transrectal								
Transvaginal								
Transurethral								
Intravascular								
Peripheral vessel (Note 2)								
Laparoscopic								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Other (specify)								

N = new indication; P = previously cleared by FDA K180067

Note 1 Note 2 For example: Breast, Thyroid, Testis For example: Carotid, Arterial, Venous

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name:

# 10V4 Curved Array Transducer

Intended Use:

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

					Mode of Ope	eration		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Fetal								
Abdominal	Р	Р	Р		Р	Р	BMCD	
Intraoperative								
Intraoperative Neurological								
Pediatric	Р	Р	Р		Р	Р	BMCD	
Small Organ (Note 1)								
Neonatal Cephalic	Р	Р	Р		Р	Р	BMCD	
Adult Cephalic								
Cardiac	Р	Р	Р	Р	Р	Р	BMCD	
Trans-esophageal								
Transrectal								
Transvaginal								
Transurethral								
Intravascular								
Peripheral vessel (Note 2)								
Laparoscopic								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Other (specify)								

N = new indication; P = previously cleared by FDA K183575

Note 1

For example: Breast, Thyroid, Testis For example: Carotid, Arterial, Venous

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name:

#### **CW2 Continuous Wave Transducer**

Intended Use:

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

	Mode of Operation								
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Specify)	Other (Specify)	
Ophthalmic									
Fetal									
Abdominal									
Intraoperative									
Intraoperative Neurological									
Pediatric				Р					
Small Organ (Note 1)									
Neonatal Cephalic									
Adult Cephalic									
Cardiac				Р					
Trans-esophageal									
Transrectal									
Transvaginal									
Transurethral									
Intravascular									
Peripheral vessel (Note 2)									
Laparoscopic									
Musculo-skeletal Conventional									
Musculo-skeletal Superficial									
Other (specify)									

N = new indication; P = previously cleared by FDA K183575

Note 1 Note 2 For example: Breast, Thyroid, Testis For example: Carotid, Arterial, Venous

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name: Intended Use:

### **CW5 Continuous Wave Transducer**

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

	Mode of Operation								
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Specify)	Other (Specify)	
Ophthalmic									
Fetal									
Abdominal									
Intraoperative									
Intraoperative Neurological									
Pediatric				Р					
Small Organ (Note 1)									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Trans-esophageal									
Transrectal									
Transvaginal									
Transurethral									
Intravascular									
Peripheral vessel (Note 2)				Р					
Laparoscopic									
Musculo-skeletal Conventional									
Musculo-skeletal Superficial									
Other (specify)									

N = new indication; P = previously cleared by FDA K183575

For example: Breast, Thyroid, Testis For example: Carotid, Arterial, Venous Note 1 Note 2

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name: Intended Use:

### 10L4 Linear Array Transducer

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

					Mode of Oper	ration		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Fetal	Р	Р	Р		Р	Р	BMCD	
Abdominal	Р	Р	Р		Р	Р	BMCD	
Intraoperative								
Intraoperative Neurological								
Pediatric	Р	Р	Р		Р	Р	BMCD	
Small Organ (Note 1)	Р	Р	Р		Р	Р	BMCD	
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Trans-esophageal								
Transrectal								
Transvaginal								
Transurethral								
Intravascular								
Peripheral vessel (Note 2)	Р	Р	Р		Р	Р	BMCD	
Laparoscopic								
Musculo-skeletal Conventional	Р	Р	Р		Р	Р	BMCD	
Musculo-skeletal Superficial	Р	Р	Р		Р	Р	BMCD	
Other (specify)								

N = new indication; P = previously cleared by FDA K180067

 Note 1
 For example: Breast, Thyroid, Testis

 Note 2
 For example: Carotid, Arterial, Venous

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name:

Intended Use:

14L5 Linear Array Transducer Ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode of Ope	ration		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative								
Intraoperative Neurological								
Pediatric	Р	Р	Р		Р	Р	BMCD	
Small Organ (Note 1)	Р	Р	Р		Р	Р	BMCD	
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Trans-esophageal								
Transrectal								
Transvaginal								
Transurethral								
Intravascular								
Peripheral vessel (Note 2)	Ρ	Р	Р		Р	Р	BMCD	
Laparoscopic								
Musculo-skeletal Conventional	Р	Р	Р		Р	Р	BMCD	
Musculo-skeletal Superficial	Р	Р	Р		Р	Р	BMCD	
Other (specify)								

N = new indication; P = previously cleared by FDA K180067

Note 1 Note 2 For example: Breast, Thyroid, Testis For example: Carotid, Arterial, Venous

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name:

Intended Use:

**18L6 Linear Array Transducer** Ultrasound imaging or fluid flow analysis of the human body as follows:

				Μ	ode of Opera	tion		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative								
Intraoperative Neurological								
Pediatric	Р	Р	Р		Р	Р	BMCD	
Small Organ (Note 1)	Р	Р	Р		Р	Р	BMCD	
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Trans-esophageal								
Transrectal								
Transvaginal								
Transurethral								
Intravascular								
Peripheral vessel (Note 2)								
Laparoscopic								
Musculo-skeletal Conventional	Р	Р	Р		Р	Р	BMCD	
Musculo-skeletal Superficial	Р	Р	Р		Р	Р	BMCD	
Other (specify)								

N = new indication; P = previously cleared by FDA K180067

Note 1 Note 2 For example: Breast, Thyroid, Testis For example: Carotid, Arterial, Venous

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name:

Intended Use:

**5C1 Curved Array Transducer** Ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode of Ope	ration		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Fetal	Р	Р	Р		Р	Р	BMCD	
Abdominal	Р	Р	Р		Р	Р	BMCD	
Intraoperative								
Intraoperative Neurological								
Pediatric	Р	Р	Р		Р	Р	BMCD	
Small Organ (Note 1)								
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Trans-esophageal								
Transrectal								
Transvaginal								
Transurethral								
Intravascular								
Peripheral vessel (Note 2)								
Laparoscopic								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Other (specify)								

N = new indication; P = previously cleared by FDA K180067

Note 1 Note 2

For example: Breast, Thyroid, Testis For example: Carotid, Arterial, Venous

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name:

Intended Use:

**9C3 Curved Array Transducer** Ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation								
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Specify)	Other (Specify)	
Ophthalmic									
Fetal	Р	Р	Р		Р	Р	BMCD		
Abdominal	Р	Р	Р		Р	Р	BMCD		
Intraoperative									
Intraoperative Neurological									
Pediatric	Р	Р	Р		Р	Р	BMCD		
Small Organ (Note 1)									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Trans-esophageal									
Transrectal									
Transvaginal									
Transurethral									
Intravascular									
Peripheral vessel (Note 2)									
Laparoscopic									
Musculo-skeletal Conventional	Р	Р	Р		Р	Р	BMCD		
Musculo-skeletal Superficial									
Other (specify)									

N = new indication; P = previously cleared by FDA K180067

Note 1 For example: Breast, Thyroid, Testis Note 2 For example: Carotid, Arterial, Venous

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name:

Intended Use:

**9EC4 Endocavity Transducer** Ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode of Oper	ration		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative								
Intraoperative Neurological								
Pediatric								
Small Organ (Note 1)								
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Trans-esophageal								
Transrectal	Р	Р	Р		Р	Р	BMCD	
Transvaginal	Р	Р	Р		Р	Р	BMCD	
Transurethral								
Intravascular								
Peripheral vessel (Note 2)								
Laparoscopic								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Other (specify)								

N = new indication; P = previously cleared by FDA K180067

Note 1 Note 2

For example: Breast, Thyroid, Testis For example: Carotid, Arterial, Venous

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

510 (k) Number (if known):

Device Name:

Intended Use:

V5Ms Multiplane TEE Transducer Ultrasound imaging or fluid flow analysis of the human body as follows:

					Mode of Oper	ration		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative								
Intraoperative Neurological								
Pediatric								
Small Organ (Note 1)								
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Trans-esophageal	Р	Р	Р	Р	Р	Р	BMCD	
Transrectal								
Transvaginal								
Transurethral								
Intravascular								
Peripheral vessel (Note 2)								
Laparoscopic								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Other (specify)								

N = new indication; P = previously cleared by FDA K183575

Note 1 Note 2

For example: Breast, Thyroid, Testis For example: Carotid, Arterial, Venous

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

# Indications for Use

510(k) Number (if known)

# K202683

Device Name ACUSON P500 Ultrasound System

# Indications for Use (Describe)

The ACUSON P500 ultrasound imaging system is intended for the following applications: Fetal, Abdominal (including liver), Pediatric, Small Parts, Transcranial, OB/GYN(useful for visualization of the ovaries, follicles, uterus and other pelvic structures), Pelvic, Neonatal, Cardiac, IntraCardiac, Vascular(including Peripheral Vessel), Musculoskeletal, Superficial Musculoskeletal, and Urology applications.

The system also provides the ability to measure anatomical structures fetal, abdominal, small organ, transrectal, transvaginal, cardiovascular, peripheral vessel, musculoskeletal (conventional), and musculoskeletal (superficial) and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system.

This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Society of Echocardiography Carotid Intima-Media Thickness Task Force. Endorsed by the Society for Vascular Imaging."

The ACUSON Acunav Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.

Type of Use (Select one or both, as applicable)	
Prescription Use (Part 21 CFR 801 Subpart D)	Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number (if known):

Device Name: Intended Use:

ACUSON P500<sup>™</sup> Ultrasound System Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applic	ation	Mod	Mode of Operation								
Other ( Track1 Only)	Specific (Tracks1l& 3)	В	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)		
Ophthalmic	Ophthalmic										
	Fetal	Р	Р	Р	Р	Р	Р	BMDC	Note 2, 3, 4, 11, 12, 16		
	Abdominal	Р	Р	Р	Р	Р	Р	BMDC	Note 2, 3, 4, 11, 12, 16		
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
Fetal	Pediatric										
Imaging & Other	SmallOrgan (Note 1)	Ρ	Ρ	Р		Р	Р	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16		
	Neonatal Cephalic				Ν						
	Adult Cephalic				N						
	Trans-rectal	Р	Р	Р		Р	Р	BMDC	Note 2, 3, 4, 11, 12, 16		
	Trans-vaginal	Р	Р	Р		Р	Р	BMDC	Note 2, 3, 4, 11, 12, 16		
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)	Ρ	Ρ	Р		Р	Р	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16		
	Musculo-skel. (Superfic)	Р	Ρ	Р		Р	Р	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16		
	Intra -vascular										
	Other (Specify)										
	Cardiac Adult	Р	Р	Р	Р	Р	Р	BMDC	Note 2, 4, 6, 7, 8, 10, 12, 16		
Cardiac	Cardiac Pediatric	Ν	Ν	Ν	N	Ν	N	BMDC	Note 2, 4, 6, 7, 10, 12, 16		
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-Cardiac	Ν	Ν	N	N	N	N	BMDC	Note 2, 4, 10, 12, 14, 15, 16		
	Other (Specify)										
Peripheral	Peripheral vessel	Р	Р	Р	N	Р	Р	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16		
Vessel	Other (Specify)										

N = new indication; P = previously cleared

Note 1 For example: breast, testes, thyroid, prostate, etc. Note 6 Stress Echo Note 2 Dynamic TCE Technology Note 7 eSieMeasure Note 3 Advanced SieClear Note 8 eSieScan AHP DTI Note 4 eSielmage Note 9 Note 10 Note 5 For example: abdominal, vascular (upper and lower) Note 11 Note 12 Panoramic 2D Imaging (SieScape) Clarify VE Needle Visualization Note 13 Note 14 Intracardiac Echocardiography (ICE) Imaging Note 15 CARTOSOUND Communication Note 16 Probe Saver

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510(k) Number (if known):

Device Name	9:	P4-2 P ACUS	hased <b>DN P5</b>	Array Tra 00 <sup>™</sup> Ultra	nsducer fo	or use with: / <b>stem</b>						
Intended Use	9:	Diagno	Diagnostic imaging or fluid flow analysis of the human body as follows:									
Clinical Appli	cation	Mod	Mode of Operation									
Other ( Track1 Only)	Specific (Tracks1l& 3)	в	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)			
Ophthalmic	Ophthalmic											
	Fetal	Р	Р	Р	Р	Р	Р	BMDC	Note 2, 4, 12,16			
	Abdominal	Р	Р	Р	Р	Р	Р	BMDC	Note 2, 4, 12,16			
	Intra-operative											
	Intra-operative (Neuro)											
	Laparoscopic											
Fetal	Pediatric											
Imaging & Other	SmallOrgan (Note 1)											
	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal											
	Trans-vaginal											
	Trans-urethral											
	Trans-esoph. (non-Card.)											
	Musculo-skel. (Convent.)											
	Musculo-skel. (Superfic)											
	Intra-vascular											
	Other (Specify)											
	Cardiac Adult	Р	Р	Р	Р	Р	Р	BMDC	Note 2, 4, 6, 7, 8, 10, 12, 16			
Cardiac	Cardiac Pediatric											
	Intra-vascular (Cardiac)											
	Trans-esophageal (Cardiac)											
	Intra-cardiac											
	Other (Specify)											
Peripheral	Peripheral vessel (Note 5)											
Vessel	Other (Specify)											

N = new indication; P = previously cleared K150050

Note 1	For example: breast, testes, thyroid, prostate, etc.	Note 6	Stress Echo
Note 2	Dynamic TCE Technology	Note 7	eSieMeasure
Note 3	Advanced SieClear	Note 8	eSieScan
Note 4	eSielmage	Note 9	AHP
Note 5	For example: abdominal, vascular (upper and lower)	Note 10	DTI
		Note 11	Panoramic 2D Imaging (SieScape)
		Note 12	Clarify VE
		Note 13	Needle Visualization
		Note 14	Intracardiac Echocardiography (ICE) Imaging
		Note 15	CARTOSOUND Communication
		Note 16	Probe Saver

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510(k) Number (if known):

 

 Device Name:
 CH5-2 Curved Array Transducer for use with: ACUSON P500<sup>™</sup> Ultrasound System

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

Clinical Applic	cation	Mod	Mode of Operation							
Other ( Track1 Only)	Specific (Tracks1l& 3)	в	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)	
Ophthalmic	Ophthalmic									
	Fetal	Р	Р	Р		Р	Р	BMDC	Note 2, 3, 4, 11, 12, 16	
	Abdominal	Р	Р	Р		Р	Р	BMDC	Note 2, 3, 4, 11, 12, 16	
	Intra-operative									
	Intra-operative (Neuro)									
	Laparoscopic									
Fetal	Pediatric									
Imaging & Other	SmallOrgan (Note 1)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)	Р	Р	Р		Р	Р	BMDC	Note 2, 3, 4, 11, 12, 16	
	Musculo-skel. (Superfic)									
	Intra-vascular									
	Other (Specify)									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Intra-vascular (Cardiac)									
	Trans-esophageal (Cardiac)									
	Intra-cardiac									
	Other (Specify)									
Peripheral	Peripheral vessel (Note 5)	Ρ	Ρ	Р		Р	Р	BMDC	Note 2, 3, 4, 11, 12, 16	
Vessel	Other (Specify)									

N = new indication; P = previously cleared K150050

Note 1	For example: breast, testes, thyroid, prostate, etc.	Note 6	Stress Echo
Note 2	Dynamic TCE Technology	Note 7	eSieMeasure
Note 3	Advanced SieClear	Note 8	eSieScan
Note 4	eSielmage	Note 9	AHP
Note 5	For example: abdominal, vascular (upper and lower)	Note 10	DTI
		Note 11	Panoramic 2D Imaging (SieScape)
		Note 12	Clarify VE
		Note 13	Needle Visualization
		Note 14	Intracardiac Echocardiography (ICE) Imaging
		Note 15	CARTOSOUND Communication
		Note 16	Probe Saver

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Concurrence of Center for Devices and Radiological Health (CDRH) (Signature) 510(k)\_\_\_\_\_

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510(k) Number (if known):

Device Nam			VF10-5 Linear Array Transducer for use with: ACUSON P500 <sup>™</sup> Ultrasound System Diagnostic imaging or fluid flow analysis of the human body as follows:									
Clinical Appli	cation	Mod	Mode of Operation									
Other ( Track1 Only)	Specific (Tracks1l& 3)	в	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)			
Ophthalmic	Ophthalmic											
	Fetal											
	Abdominal											
	Intra-operative											
	Intra-operative (Neuro)											
	Laparoscopic											
Fetal	Pediatric											
Imaging & Other	SmallOrgan (Note 1)	Р	Р	Ρ		Р	Р	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16			
	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal											
	Trans-vaginal											
	Trans-urethral											
	Trans-esoph. (non-Card.)											
	Musculo-skel. (Convent.)	Р	Р	Ρ		Р	Р	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16			
	Musculo-skel. (Superfic)											
	Intra-vascular											
	Other (Specify)											
	Cardiac Adult											
Cardiac	Cardiac Pediatric											
	Intra-vascular (Cardiac)											
	Trans-esophageal (Cardiac)											
	Intra-cardiac											
	Other (Specify)											
Peripheral	Peripheral vessel (Note 5)	Р	Р	Р		Р	Р	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16			
Vessel	Other (Specify)											

N = new indication; P = previously cleared K150050

Note 1	For example: breast, testes, thyroid, prostate, etc.	Note 6	Stress Echo
Note 2	Dynamic TCE Technology	Note 7	eSieMeasure
Note 3	Advanced SieClear	Note 8	eSieScan
Note 4	eSielmage	Note 9	AHP
Note 5	For example: abdominal, vascular (upper and lower)	Note 10	DTI
		Note 11	Panoramic 2D Imaging (SieScape)
		Note 12	Clarify VE
		Note 13	Needle Visualization
		Note 14	Intracardiac Echocardiography (ICE) Imaging
		Note 15	CARTOSOUND Communication
		Note 16	Probe Saver

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510(k)\_\_

510(k) Number (if known):

 Device Name:
 EC9-4 Curved Array Transducer for use with:

 ACUSON P500<sup>™</sup> Ultrasound System

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

Clinical Applic	ation	Mod	Mode of Operation							
Other ( Track1 Only)	Specific (Tracks1l& 3)	в	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)	
Ophthalmic	Ophthalmic									
	Fetal	Р	Р	Р		Р	Р	BMDC	Note 2, 3, 4, 11, 12, 16	
	Abdominal									
	Intra-operative									
	Intra-operative (Neuro)									
	Laparoscopic									
Fetal	Pediatric									
Imaging & Other	SmallOrgan (Note 1)	Р	Р	Р		Р	Р	BMDC	Note 2, 3, 4, 11, 12, 16	
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal	Р	Р	Р		Р	Р	BMDC	Note 2, 3, 4, 11, 12, 16	
	Trans-vaginal	Р	Р	Р		Р	Р	BMDC	Note 2, 3, 4, 11, 12, 16	
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic)									
	Intra-vascular									
	Other (Specify)									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Intra-vascular (Cardiac)									
	Trans-esophageal (Cardiac)									
	Intra-cardiac									
	Other (Specify)									
Peripheral	Peripheral vessel (Note 5)									
Vessel	Other (Specify)									

N = new indication; P = previously cleared K150050

Note 1 For example: breast, testes, thyroid, prostate, etc. Note 6 Stress Echo	
Note 2 Dynamic TCE Technology Note 7 eSieMeasure	
Note 3 Advanced SieClear Note 8 eSieScan	
Note 4 eSielmage Note 9 AHP	
Note 5 For example: abdominal, vascular (upper and lower) Note 10 DTI	
Note 11 Panoramic 2D Imaging (SieScape)	
Note 12 Clarify VE	
Note 13 Needle Visualization	
Note 14 Intracardiac Echocardiography (ICE) Imaging	
Note 15 CARTOSOUND Communication	
Note 16 Probe Saver	

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510(k) Number (if known	own)	):
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Device Name:

Intended Use:

VF13-5 Linear Transducer for use with: ACUSON P500<sup>™</sup> Ultrasound System Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applic	inical Application Mode of Operation								
Other ( Track1 Only)	Specific (Tracks1l& 3)	в	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric								
Imaging & Other	SmallOrgan (Note 1)	Р	Р	Р		Р	Р	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)	Ρ	Ρ	Р		Р	Р	BMDC	Note 2, 3, 4 , 9, 11, 12, 13, 16
	Intra-vascular								
	Other (Specify)								
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel (Note 5)	Ρ	Ρ	Р		Р	Р	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16
Vessel	Other (Specify)								

N = new indication; P = previously cleared K150050

Note 1	For example: breast, testes, thyroid, prostate, etc.	Note 6	Stress Echo
Note 2	Dynamic TCE Technology	Note 7	eSieMeasure
Note 3	Advanced SieClear	Note 8	eSieScan
Note 4	eSielmage	Note 9	AHP
Note 5	For example: abdominal, vascular (upper and lower)	Note 10	DTI
		Note 11	Panoramic 2D Imaging (SieScape)
		Note 12	Clarify VE
		Note 13	Needle Visualization
		Note 14	Intracardiac Echocardiography (ICE) Imaging
		Note 15	CARTOSOUND Communication
		Note 16	Probe Saver
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510(k) Number (if known):

Device Name:

Intended Use:

VF16-5 Transducer for use with: ACUSON P500<sup>™</sup> Ultrasound System

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

Clinical Application			Mode of Operation							
Other ( Track1 Only)	Specific (Tracks1l& 3)	в	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)	
Ophthalmic	Ophthalmic									
	Fetal									
	Abdominal									
	Intra-operative									
	Intra-operative (Neuro)									
	Laparoscopic									
Fetal	Pediatric									
Imaging & Other	SmallOrgan (Note 1)	Р	Р	Р		Р	Р	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16	
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic)	Ρ	Ρ	Р		Р	Р	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16	
	Intra-vascular									
	Other (Specify)									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Intra-vascular (Cardiac)									
	Trans-esophageal (Cardiac)									
	Intra-cardiac									
	Other (Specify)									
Peripheral	Peripheral vessel (Note 5)									
Vessel	Other (Specify)		144.040							

N = new indication; P = previously cleared K141846

Note 1	For example: breast, testes, thyroid, prostate, etc.	Note 6	Stress Echo
Note 2	Dynamic TCE Technology	Note 7	eSieMeasure
Note 3	Advanced SieClear	Note 8	eSieScan
Note 4	eSielmage	Note 9	AHP
Note 5	For example: abdominal, vascular (upper and lower)	Note 10	DTI
		Note 11	Panoramic 2D Imaging (SieScape)
		Note 12	Clarify VE
		Note 13	Needle Visualization
		Note 14	Intracardiac Echocardiography (ICE) Imaging
		Note 15	CARTOSOUND Communication
		Note 16	Probe Saver

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510(k) Number (if known):

Device Name:

P8-4 Transducer for use with:

Intended Use:

ACUSON P500<sup>TM</sup> Ultrasound System

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

Clinical Application		Mod	Mode of Operation							
Other ( Track1 Only)	Specific (Tracks1l& 3)	В	м	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)	
Ophthalmic	Ophthalmic									
	Fetal									
	Abdominal	Р	Р	Р		Р	Р	BMDC	Note 2, 4, 12, 16	
	Intra-operative									
	Intra-operative (Neuro)									
	Laparoscopic									
Fetal	Pediatric									
Imaging & Other	SmallOrgan (Note 1)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic)									
	Intra-vascular									
	Other (Specify)									
	Cardiac Adult									
Cardiac	Cardiac Pediatric	Р	Р	Р	Р	Р	Р	BMDC	Note 2, 4, 6, 7, 10, 12, 16	
	Intra-vascular (Cardiac)									
	Trans-esophageal (Cardiac)									
	Intra-cardiac									
	Other (Specify)									
Peripheral	Peripheral vessel (Note 5)									
Vessel	Other (Specify)									

N = new indication; P = previously cleared by K141846, K161787

Note 1	For example: breast, testes, thyroid, prostate, etc.	Note 6	Stress Echo
Note 2	Dynamic TCE Technology	Note 7	eSieMeasure
Note 3	Advanced SieClear	Note 8	eSieScan
Note 4	eSielmage	Note 9	AHP
Note 5	For example: abdominal, vascular (upper and lower)	Note 10	DTI
		Note 11	Panoramic 2D Imaging (SieScape)
		Note 12	Clarify VE
		Note 13	Needle Visualization
		Note 14	Intracardiac Echocardiography (ICE) Imaging
		Note 15	CARTOSOUND Communication
		Note 16	Probe Saver

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510(k) Number (if known):

Device Name:

Intended Use:

L10-5v Transducer for use with: ACUSON P500<sup>™</sup> Ultrasound System

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

Clinical Application		Mod	Mode of Operation							
Other ( Track1 Only)	Specific (Tracks1l& 3)	В	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)	
Ophthalmic	Ophthalmic									
	Fetal									
	Abdominal									
	Intra-operative									
	Intra-operative (Neuro)									
	Laparoscopic									
Fetal	Pediatric									
Imaging & Other	SmallOrgan (Note 1)	Р	Р	Р		Р	Р	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16	
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)	Р	Р	Р		Р	Р	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16	
	Musculo-skel. (Superfic)									
	Intra-vascular									
	Other (Specify)									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Intra-vascular (Cardiac)									
	Trans-esophageal (Cardiac)									
	Intra-cardiac									
	Other (Specify)									
Peripheral	Peripheral vessel (Note 5)	Ρ	Р	Р		Р	Р	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16	
Vessel	Other (Specify)									

N = new indication; P = previously cleared K161787

Note 1	For example: breast, testes, thyroid, prostate, etc.	Note 6	Stress Echo
Note 2	Dynamic TCE Technology	Note 7	eSieMeasure
Note 3	Advanced SieClear	Note 8	eSieScan
Note 4	eSielmage	Note 9	AHP
Note 5	For example: abdominal, vascular (upper and lower)	Note 10	DTI
		Note 11	Panoramic 2D Imaging (SieScape)
		Note 12	Clarify VE
		Note 13	Needle Visualization
		Note 14	Intracardiac Echocardiography (ICE) Imaging
		Note 15	CARTOSOUND Communication
		Note 16	Probe Saver

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510(k) Number (if known):

Device Name:

Intended Use:

CW2 Transducer for use with: ACUSON P500<sup>™</sup> Ultrasound System

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

Clinical Application		Mod	Mode of Operation								
Other ( Track1 Only)	Specific (Tracks1l& 3)	в	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)		
Ophthalmic	Ophthalmic										
	Fetal										
	Abdominal										
	Intra-operative										
	Intra-operative (Neuro)										
	Laparoscopic										
Fetal	Pediatric										
Imaging & Other	SmallOrgan (Note 1)										
	Neonatal Cephalic				Р						
	Adult Cephalic				Р						
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
	Cardiac Adult				Р						
Cardiac	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral	Peripheral vessel (Note 5)				Р						
Vessel	Other (Specify)										

N = new indication; P = previously cleared K141846

Note 1	For example: breast, testes, thyroid, prostate, etc.	Note 6	Stress Echo
Note 2	Dynamic TCE Technology	Note 7	eSieMeasure
Note 3	Advanced SieClear	Note 8	eSieScan
Note 4	eSielmage	Note 9	AHP
Note 5	For example: abdominal, vascular (upper and lower)	Note 10	DTI
		Note 11	Panoramic 2D Imaging (SieScape)
		Note 12	Clarify VE
		Note 13	Needle Visualization
		Note 14	Intracardiac Echocardiography (ICE) Imaging
		Note 15	CARTOSOUND Communication
		Note 16	Probe Saver

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510(k) Number (if known):

Device Name:

Intended Use:

CW5 Transducer for use with: ACUSON P500<sup>™</sup> Ultrasound System

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

Clinical Application		Mod	Mode of Operation							
Other ( Track1 Only)	Specific (Tracks1l& 3)	В	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)	
Ophthalmic	Ophthalmic									
	Fetal									
	Abdominal									
	Intra-operative									
	Intra-operative (Neuro)									
	Laparoscopic									
Fetal	Pediatric									
Imaging & Other	SmallOrgan (Note 1)									
	Neonatal Cephalic				Р					
	Adult Cephalic				Р					
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic)									
	Intra-vascular									
	Other (Specify)									
	Cardiac Adult				Р					
Cardiac	Cardiac Pediatric				Р					
	Intra-vascular (Cardiac)									
	Trans-esophageal (Cardiac)									
	Intra-cardiac									
	Other (Specify)									
Peripheral	Peripheral vessel (Note 5)				Р					
Vessel	Other (Specify)									

N = new indication; P = previously cleared by K141846

Note 1	For example: breast, testes, thyroid, prostate, etc.	Note 6	Stress Echo
Note 2	Dynamic TCE Technology	Note 7	eSieMeasure
Note 3	Advanced SieClear	Note 8	eSieScan
Note 4	eSielmage	Note 9	AHP
Note 5	For example: abdominal, vascular (upper and lower)	Note 10	DTI
		Note 11	Panoramic 2D Imaging (SieScape)
		Note 12	Clarify VE
		Note 13	Needle Visualization
		Note 14	Intracardiac Echocardiography (ICE) Imaging
		Note 15	CARTOSOUND Communication
		Note 16	Probe Saver

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Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

510(k)\_\_\_

510(k) Number (if known):

 

 Device Name:
 AcuNav 8F Transducer for use with: ACUSON P500<sup>™</sup> Diagnostic Ultrasound System

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

Clinical Application			Mode of Operation								
Other ( Track1 Only)	Specific (Tracks1l& 3)	В	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)		
Ophthalmic	Ophthalmic										
	Fetal										
	Abdominal										
	Intra-operative										
	Intra-operative (Neuro)										
	Laparoscopic										
Fetal	Pediatric										
Imaging & Other	SmallOrgan (Note 1)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)										
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
	Cardiac Adult										
Cardiac	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac	Р	Р	Р	Р	Р	Р	BMDC	Note 2, 4, 10, 12, 14, 16		
	Other (Specify)										
Peripheral	Peripheral vessel (Note 5)										
Vessel	Other (Specify)										

N = new indication; P = previously cleared K141846

Note 1	For example: breast, testes, thyroid, prostate, etc.	Note 6	Stress Echo
Note 2	Dynamic TCE Technology	Note 7	eSieMeasure
Note 3	Advanced SieClear	Note 8	eSieScan
Note 4	eSielmage	Note 9	AHP
Note 5	For example: abdominal, vascular (upper and lower)	Note 10	DTI
		Note 11	Panoramic 2D Imaging (SieScape)
		Note 12	Clarify VE
		Note 13	Needle Visualization
		Note 14	Intracardiac Echocardiography (ICE) Imaging
		Note 15	CARTOSOUND Communication
		Note 16	Probe Saver

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510(k) Number (if known):

AcuNav 10F Transducer for use with: Device Name: ACUSON P500<sup>™</sup> Diagnostic Ultrasound System Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows: **Clinical Application** Mode of Operation Other Specific Color Power Combined Other ( Track1 Only) PWD CWD в М (Tracks1l& 3) Doppler Doppler (Specify) (Specify) Ophthalmic Ophthalmic Fetal Abdominal Intra-operative Intra-operative (Neuro) Laparoscopic Fetal Pediatric Imaging & Other SmallOrgan (Note 1) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic) Intra-vascular Other (Specify) Cardiac Adult Cardiac Pediatric Cardiac Intra-vascular (Cardiac) Trans-esophageal (Cardiac) Р Р Р Р Р BMDC Р Note 2, 4, 10, 12, 14, 16 Intra-cardiac Other (Specify) Peripheral vessel Peripheral (Note 5) Vessel Other (Specify)

N = new indication; P = previously cleared K141846

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510(k) Number (if known):

 

 Device Name:
 Soundstar 10F Transducer for use with: ACUSON P500<sup>™</sup> Diagnostic Ultrasound System

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

 Objected Application
 Made of Occurring

Clinical Applic	Mode of Operation									
Other ( Track1 Only)	Specific (Tracks1l& 3)	в	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)	
Ophthalmic	Ophthalmic									
	Fetal									
	Abdominal							1		
	Intra-operative									
	Intra-operative (Neuro)									
	Laparoscopic									
Fetal	Pediatric									
Imaging & Other	SmallOrgan (Note 1)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic)									
	Intra-vascular									
	Other (Specify)									
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Intra-vascular (Cardiac)									
	Trans-esophageal (Cardiac)									
	Intra-cardiac	Р	Р	Р	Р	Р	Р	BMDC	Note 2, 4, 10, 12, 14, 15, 16	
	Other (Specify)									
Peripheral	Peripheral vessel (Note 5)									
Vessel	Other (Specify)									

N = new indication; P = previously cleared K141846

Note 1	For example: breast, testes, thyroid, prostate, etc.	Note 6	Stress Echo
Note 2	Dynamic TCE Technology	Note 7	eSieMeasure
Note 3	Advanced SieClear	Note 8	eSieScan
Note 4	eSielmage	Note 9	AHP
Note 5	For example: abdominal, vascular (upper and lower)	Note 10	DTI
		Note 11	Panoramic 2D Imaging (SieScape)
		Note 12	Clarify VE
		Note 13	Needle Visualization
		Note 14	Intracardiac Echocardiography (ICE) Imaging
		Note 15	CARTOSOUND Communication
		Note 16	Probe Saver
		Note To	

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510(k) Number (if known):

Soundstar eco 8F Transducer for use with: Device Name: ACUSON P500<sup>™</sup> Diagnostic Ultrasound System Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows: **Clinical Application** Mode of Operation Other Specific Color Power Combined Other ( Track1 Only) PWD CWD в М (Tracks1l& 3) Doppler Doppler (Specify) (Specify) Ophthalmic Ophthalmic Fetal Abdominal Intra-operative Intra-operative (Neuro) Laparoscopic Fetal Pediatric Imaging & Other SmallOrgan (Note 1) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic) Intra-vascular Other (Specify) Cardiac Adult Cardiac Pediatric Cardiac Intra-vascular (Cardiac) Trans-esophageal (Cardiac) BMDC Р Р Р Р Р Р Note 2, 4, 10, 12, 14, 15, 16 Intra-cardiac Other (Specify) Peripheral vessel Peripheral (Note 5) Vessel Other (Specify)

N = new indication; P = previously cleared K141846

Note 1	For example: breast, testes, thyroid, prostate, etc.	Note 6	Stress Echo
Note 2	Dynamic TCE Technology	Note 7	eSieMeasure
Note 3	Advanced SieClear	Note 8	eSieScan
Note 4	eSielmage	Note 9	AHP
Note 5	For example: abdominal, vascular (upper and lower)	Note 10	DTI
		Note 11	Panoramic 2D Imaging (SieScape)
		Note 12	Clarify VE
		Note 13	Needle Visualization
		Note 14	Intracardiac Echocardiography (ICE) Imaging
		Note 15	CARTOSOUND Communication
		Note 16	Probe Saver

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510(k) Number (if known):

Soundstar eco 10F Transducer for use with: Device Name: ACUSON P500<sup>™</sup> Diagnostic Ultrasound System Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows: **Clinical Application** Mode of Operation Other Specific Color Power Combined Other ( Track1 Only) PWD CWD в М (Tracks1l& 3) Doppler Doppler (Specify) (Specify) Ophthalmic Ophthalmic Fetal Abdominal Intra-operative Intra-operative (Neuro) Laparoscopic Fetal Pediatric Imaging & Other SmallOrgan (Note 1) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic) Intra-vascular Other (Specify) Cardiac Adult Cardiac Pediatric Cardiac Intra-vascular (Cardiac) Trans-esophageal (Cardiac) Р Р Р Р BMDC Р Р Note 2, 4, 10, 12, 14, 15, 16 Intra-cardiac Other (Specify) Peripheral vessel Peripheral (Note 5) Vessel Other (Specify)

N = new indication; P = previously cleared K141846

Note 1	For example: breast, testes, thyroid, prostate, etc.	Note 6	Stress Echo
Note 2	Dynamic TCE Technology	Note 7	eSieMeasure
Note 3	Advanced SieClear	Note 8	eSieScan
Note 4	eSielmage	Note 9	AHP
Note 5	For example: abdominal, vascular (upper and lower)	Note 10	DTI
		Note 11	Panoramic 2D Imaging (SieScape)
		Note 12	Clarify VE
		Note 13	Needle Visualization
		Note 14	Intracardiac Echocardiography (ICE) Imaging
		Note 15	CARTOSOUND Communication
		Note 16	Probe Saver

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# Indications for Use

510(k) Number *(if known)* K202683

# Device Name

ACUSON NX3 Diagnostic Ultrasound System ACUSON NX3 Elite Diagnostic Ultrasound System

# Indications for Use (Describe)

For ACUSON NX3

The ACUSON NX3 ultrasound imaging system is intended for the following applications: Fetal Abdominal (including liver), Pediatric, Small Parts (Small Organ), Neonatal Cephalic, Adult Cephalic, Transcranial, OB/GYN, Pelvic, Neonatal, Cardiac, Vascular (including Peripheral Vessel), Musculoskeletal, Superficial Musculoskeletal and Urology applications.

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

## For ACUSON NX3 Elite

The ACUSON NX3 Elite ultrasound imaging system is intended for the following applications: Fetal, Abdominal (including liver, intra-operative), Pediatric, Small Parts (Small Organ including intra-operative), Neonatal Cephalic, Adult Cephalic, Transcranial, OB/GYN, Pelvic, Neonatal, Cardiac(including Transesophageal), Vascular (including Peripheral Vessel, intra-operative), Musculoskeletal, Superficial Musculoskeletal and Urology applications.

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

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system.

Note: This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Society of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Medicine."

Type of Use	(Select one	or both,	as applicable)	
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Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number (if known):

Device Name:

Intended Use:

ACUSON NX3 Elite<sup>™</sup> Diagnostic Ultrasound System Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation								
Other ( Track1 Only)	Specific (Tracks1l& 3)	В	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)	
Ophthalmic	Ophthalmic	1								
	Fetal	Р	Р	Р		Р	Р	Р		
	Abdominal	Р	Р	Р		Р	Р	Р		
	Intra-operative (Note 2)	Р	Р	Р		Р	Р	Р		
	Intra-operative (Neuro)									
Fetal	Laparoscopic Pediatric	Р	Р	Р		Р	Р	Р		
Imaging & Other	SmallOrgan (Note 1)	Р	Р	Р		Р	Р	Р		
	Neonatal Cephalic	Р	Р	Р		Р	Р	Р		
	Adult Cephalic	Р	Р	Р	Р	Р	Р	Р		
	Trans-rectal	Р	Р	Р		Р	Р	Р		
	Trans-vaginal	Р	Р	Р		Р	Р	Р		
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)	Р	Р	Р		Р	Р	Р		
	Musculo-skel. (Superfic)	Р	Р	Р		Р	Р	Р		
	Intra -vascular Other (Specify)									
	Cardiac Adult	Р	Р	Р	Р	Р	Р	Р		
Cardiac	Cardiac Pediatric	Р	Р	Р	Р	Р	Р	Р		
	Intra-vascular (Cardiac)									
	Trans-esophageal (Cardiac)	Р	Р	Р	Р	Р	Р	Р		
	Intra-Cardiac									
	Other (Specify)									
Peripheral	Peripheral vessel	Р	Р	Р		Р	Р	Р		
Vessel	Other (Specify)									

N = new indication; P = previously cleared by (K173957)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc. Note 2 For example: abdominal, vascular

Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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510(k) Number (if known):

ACUSON NX3<sup>™</sup> Diagnostic Ultrasound System

Device Name: Intended Use:

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

Clinical Application		Mod	Mode of Operation								
Other ( Track1 Only)	Specific (Tracks1l& 3)	В	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)		
Ophthalmic	Ophthalmic										
	Fetal	Ρ	Р	Р		Р	Р	Р			
	Abdominal	Р	Р	Р		Р	Р	Р			
	Intra-operative (Note 2)										
	Intra-operative (Neuro)										
Fatal	Laparoscopic										
Fetal	Pediatric	Р	Р	Р		Р	Р	Р			
Imaging & Other	SmallOrgan (Note 1)	Р	Р	Р		Р	Р	Р			
	Neonatal Cephalic	Р	Р	Р		Р	Р	Р			
	Adult Cephalic	Р	Р	Р		Р	Р	Р			
	Trans-rectal	Р	Р	Р		Р	Р	Р			
	Trans-vaginal	Р	Р	Р		Р	Р	Р			
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)	Р	Р	Р		Р	Р	Р			
	Musculo-skel. (Superfic) Intra -vascular	Р	Р	Р		Р	Р	Р			
	Other										
	(Specify)										
	Cardiac Adult	Р	Р	Р		Р	Р	Р			
Cardiac	Cardiac Pediatric	Р	Р	Р		Р	Р	Р			
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-Cardiac										
	Other (Specify)										
Peripheral	Peripheral vessel	Р	Р	Р		Р	Р	Р			
Vessel	Other (Specify)										

N = new indication; P = previously cleared by (K173957)

Note 1

Note 2

For example: breast, testes, thyroid, penis, prostate, etc. For example: abdominal, vascular Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M Note 3

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510(k) Number (if known):

Device Name:			CH5-2 Transducer for use with: ACUSON NX3 Elite <sup>™</sup> Diagnostic Ultrasound System / ACUSON NX3 <sup>™</sup> Diagnostic Ultrasound System										
Intended Use	e:	Dia	Diagnostic imaging or fluid flow analysis of the human body as follows:										
Clinical Appli	ication	Mod	e of Op	eration									
Other ( Track1 Only)	Specific (Tracks1l& 3)	В	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)				
Ophthalmic	Ophthalmic												
	Fetal	Р	Р	Р		Ρ	Р	Р					
	Abdominal	Р	Р	Р		Р	Р	Р					
	Intra-operative (Note 2)												
	Intra-operative (Neuro)												
	Laparoscopic												
Fetal	Pediatric	Р	Р	Р		Р	Р	Р					
Imaging & Other	SmallOrgan (Note 1)												
	Neonatal Cephalic												
	Adult Cephalic												
	Trans-rectal												
	Trans-vaginal												
	Trans-urethral												
	Trans-esoph. (non-Card.)												
	(non-Card.) Musculo-skel. (Convent.)												
	Musculo-skel. (Superfic)												
	Intra-vascular												
	Other (Specify)												
	Cardiac Adult												
Cardiac	Cardiac Pediatric				ļ			ļ					
	Intra-vascular (Cardiac)												
	Trans-esophageal (Cardiac)												
	Intra-cardiac												
	Other (Specify)												
Peripheral	Peripheral vessel	Р	Р	Р		Р	Р	Р					
Vessel	Other (Specify) ation; P = previously cle												

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

Note 2

For example: abdominal, vascular Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M Note 3

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510(k) Number (if known):

Device Name:

VF10-5 Linear Array Transducer for use with: ACUSON NX3 Elite<sup>™</sup> Diagnostic Ultrasound System / ACUSON NX3<sup>™</sup> Diagnostic Ultrasound System

Intended Use:

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

Clinical Application		Mode of Operation								
Other ( Track1 Only)	Specific (Tracks1l& 3)	в	м	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)	
Ophthalmic	Ophthalmic									
	Fetal									
	Abdominal	Р	Р	Р		Р	Р	Р		
	Intra-operative (Note 2)									
	Intra-operative (Neuro)									
	Laparoscopic									
Fetal	Pediatric	Р	Р	Р		Р	Р	Р		
Imaging & Other	SmallOrgan (Note 1)	Р	Р	Р		Р	Р	Р		
	Neonatal Cephalic									
	Adult Cephalic	Р	Р	Р		Р	Р	Р		
	Trans-rectal						-	-		
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)	Р	Р	Р		Р	Р	Р		
	Musculo-skel. (Superfic) Intra-vascular	Р	Р	Р		Р	Р	Р		
	Other (Specify)									
	Cardiac Adult							1		
Cardiac	Cardiac Pediatric									
	Intra-vascular (Cardiac)									
	Trans-esophageal (Cardiac)									
	Intra-cardiac									
	Other (Specify)									
Peripheral	Peripheral vessel	Р	Р	Р		Р	Р	Р		
Vessel	Other (Specify)									

N = new indication; P = previously cleared by (K173957)

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

Note 2 For example: abdominal, vascular

Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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510(k) Number (if known):

Device Name:

VF12-4 Linear Array Transducer for use with: ACUSON NX3 Elite<sup>™</sup> Diagnostic Ultrasound System / ACUSON NX3<sup>™</sup> Diagnostic Ultrasound System Diagnostic imaging or fluid flow analysis of the human body as follows:

Intended Use:

Clinical Application		Mod	Mode of Operation								
Other ( Track1 Only)	Specific (Tracks1I& 3)	в	м	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)		
Ophthalmic	Ophthalmic										
	Fetal Abdominal										
	Intra-operative	Р	Р	P		Р	Р	P			
	(Note 2) Intra-operative										
	(Neuro) Laparoscopic										
Fetal	Pediatric	Р	Р	Р		Р	Р	Р			
Imaging & Other	SmallOrgan (Note 1)	Р	Р	Р		Р	Р	Р			
	Neonatal Cephalic – NX3 Elite only	Р	Р	Р		Р	Р	Р			
	Adult Cephalic	Р	Р	Р		Р	Р	Р			
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)	Р	Р	Р		Р	Р	Р			
	Musculo-skel. (Superfic) Intra-vascular	Р	Р	Р		Р	Р	Р			
	Other (Specify)										
	Cardiac Adult										
Cardiac	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac) Intra-cardiac										
	Other (Specify)										
Peripheral	Peripheral vessel	Р	Р	Р		Р	Р	Р			
Vessel	Other (Specify)	Р	P	Г Р		۲	۲	۲			
N - n aug in -!!	tion; P = previously clea	an a ku	/// 170	057)	1	1	I	1			

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

Note 2

For example: abdominal, vascular Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M Note 3

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510(k) Number (if known):

Device Name:

Intended Use:

EC10-5w Convex Array Transducer for use with: ACUSON NX3 Elite<sup>™</sup> Diagnostic Ultrasound System Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Applie	cation	Mod	e of Op	peration					
Other ( Track1 Only)	Specific (Tracks1I& 3)	в	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal	Ρ	Ρ	Р		Р	Ρ	Ρ	
	Abdominal								
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric								
Imaging & Other	SmallOrgan (Note 1)	Р	Р	Р		Р	Р	Р	
	Neonatal Cephalic	Р	Р	Р		Р	Р	Р	
	Adult Cephalic								
	Trans-rectal	Р	Р	Р		Р	Р	Р	
	Trans-vaginal	Р	Р	Р		Р	Р	Р	
	Trans-urethral								
	Trans-esoph.								
	(non-Card.) Musculo-skel.								
	(Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-Cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel								
Vessel	Other (Specify)								

N = new indication; P = previously cleared by (K173957)

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

Note 2

For example: abdominal, vascular Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M Note 3

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510(k) Number (if known):

Device Name:

EC9-4 Convex Array Transducer for use with: ACUSON NX3 Elite<sup>™</sup> Diagnostic Ultrasound System / ACUSON NX3<sup>™</sup> Diagnostic Ultrasound System

Intended Use:

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

Clinical Appli	cation	Mod	e of Op	peration					
Other ( Track1 Only)	Specific (Tracks1I& 3)	в	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal	Ρ	Ρ	Р		Р	Ρ	Р	
	Abdominal								
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric								
Imaging & Other	SmallOrgan (Note 1)	Р	Р	Р		Р	Р	Р	
	Neonatal Cephalic - NX3 Elite Only	Р	Ρ	Р		Р	Р	Р	
	Adult Cephalic								
	Trans-rectal	Р	Р	Р		Р	Р	Р	
	Trans-vaginal	Р	Р	Р		Р	Р	Р	
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel.								
	(Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
	Cardiac Adult								
Cardiac	Cardiac Pediatric							1	
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-Cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel								
Vessel	Other (Specify)								

N = new indication; P = previously cleared by (K173957)

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

Note 2 For example: abdominal, vascular Note 3

Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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510(k) Number (if known):

CW2 Continuous Wave Doppler Transducer for use with: ACUSON NX3 Elite<sup>™</sup> Diagnostic Ultrasound System

Device Name: Intended Use:

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

Clinical Application		Mod	Mode of Operation										
Other ( Track1 Only)	Specific (Tracks1l& 3)	в	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)				
Ophthalmic	Ophthalmic												
	Fetal												
	Abdominal												
	Intra-operative (Note 2)												
	Intra-operative (Neuro)												
	Laparoscopic												
Fetal	Pediatric												
Imaging & Other	SmallOrgan (Note 1)												
	Neonatal Cephalic												
	Adult Cephalic												
	Trans-rectal												
	Trans-vaginal												
	Trans-urethral												
	Trans-esoph. (non-Card.)												
	Musculo-skel. (Convent.)												
	Musculo-skel. (Superfic)												
	Intra-vascular Other												
	(Specify)												
	Cardiac Adult				Р								
Cardiac	Cardiac Pediatric				Р								
	Intra-vascular (Cardiac)												
	Trans-esophageal (Cardiac)												
	Intra-cardiac												
	Other (Specify)												
Peripheral	Peripheral vessel												
Vessel	Other (Specify)												

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

Note 2

For example: abdominal, vascular Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M Note 3

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510(k) Number (if known):

CW5 Continuous Wave Doppler Transducer for use with: ACUSON NX3 Elite<sup>™</sup> Diagnostic Ultrasound System

Device Name: Intended Use:

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

Clinical Appli	Mod	Mode of Operation										
Other ( Track1 Only)	Specific (Tracks1l& 3)	в	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)			
Ophthalmic	Ophthalmic											
	Fetal											
	Abdominal											
	Intra-operative (Note 2)											
	Intra-operative (Neuro)											
	Laparoscopic											
Fetal	Pediatric											
Imaging & Other	SmallOrgan (Note 1)											
	Neonatal Cephalic											
	Adult Cephalic				Р							
	Trans-rectal											
	Trans-vaginal											
	Trans-urethral											
	Trans-esoph. (non-Card.)											
	Musculo-skel. (Convent.)											
	Musculo-skel. (Superfic)											
	Intra-vascular Other											
	(Specify)											
	Cardiac Adult	ľ	Ī		Р							
Cardiac	Cardiac Pediatric				Р							
	Intra-vascular (Cardiac)											
	Trans-esophageal (Cardiac)											
	Intra-cardiac											
	Other (Specify)											
Peripheral	Peripheral vessel											
Vessel	Other (Specify) tion; P = previously cle											

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

Note 2

For example: abdominal, vascular Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M Note 3

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510(k) Number (if known):

P4-2 Phased Sector Array Transducer for use with: ACUSON NX3 Elite<sup>™</sup> Diagnostic Ultrasound System / ACUSON NX3<sup>™</sup> Diagnostic Ultrasound System Diagnostic imaging or fluid flow analysis of the human body as follows:

Intended Use:

Device Name:

Clinical Applie	cation	Mode	e of Op	peration					
Other ( Track1 Only)	Specific (Tracks1l& 3)	в	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal	Ρ	Ρ	Р		Р	Р	Р	
	Abdominal	Р	Р	Р		Р	Р	Р	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric	Ρ	Ρ	Р		Р	Р	Р	
Imaging & Other	SmallOrgan (Note 1)	Р	Р	Р		Р	Р	Р	
	Neonatal Cephalic – NX3 Elite Only	Р	Р	Р		Р	Р	Р	
	Adult Cephalic	Р	Р	Р		Р	Р	Р	
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
	Cardiac Adult	Р	Р	Р	Р	Р	Р	Р	
Cardiac	Cardiac Pediatric	Р	Р	Р	Р	Р	Р	Р	
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel								
Vessel	Other (Specify)								

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

Note 2

For example: abdominal, vascular Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M Note 3

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510(k) Number (if known):

VF16-5 Transducer for use with: ACUSON NX3 Elite<sup>™</sup> Diagnostic Ultrasound System

Device Name: Intended Use:

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

Clinical Appli	cation	Mod	e of Op	peration					
Other ( Track1 Only)	Specific (Tracks1l& 3)	в	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal	Р	Р	Р		Р	Р	Р	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric	Р	Р	Р		Р	Р	Р	
Imaging & Other	SmallOrgan (Note 1)	Р	Р	Р		Р	Р	Р	
	Neonatal Cephalic								
	Adult Cephalic	Р	Р	Р		Р	Р	Р	
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	Р	Р	Р		Р	Р	Р	
	Musculo-skel. (Superfic)	Р	Р	Р		Р	Р	Р	
	Intra-vascular								
	Other (Specify)								
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel								
Vessel	Other (Specify)								

N = new indication; P = previously cleared by (K173957)

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

Note 2

For example: abdominal, vascular Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M Note 3

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Concurrence of Center for Devices and Radiological Health (CDRH) (Signature) 510(k)\_

510(k) Number (if known):

VF13-5sp Transducer for use with: ACUSON NX3 Elite<sup>™</sup> Diagnostic Ultrasound System

Device Name: Intended Use:

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

Clinical Appli	Clinical Application		e of Op	peration					
Other ( Track1 Only)	Specific (Tracks1l& 3)	в	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative (Note 2)	Р	Р	Р		Р	Р	Р	
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric	Р	Р	Р		Р	Р	Р	
Imaging & Other	SmallOrgan (Note 1)	Р	Р	Р		Р	Р	Р	
	Neonatal Cephalic								
	Adult Cephalic	Р	Р	Р		Р	Р	Р	
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	Ρ	Р	Р		Р	Р	Р	
	Musculo-skel. (Superfic)	Ρ	Р	Р		Р	Р	Р	
	Intra-vascular								
	Other (Specify)								
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac							ļ	
	Other (Specify)								
Peripheral	Peripheral vessel (Note 1)	Ρ	Р	Р		Р	Р		
Vessel	Other (Specify)								

N = new indication; P = previously cleared by (K173957)

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

Note 2

For example: abdominal, vascular, small parts Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M Note 3

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510(k) Number (if known):

Device Nam		Sys	C8F3 Transducer for use with: ACUSON NX3 Elite <sup>™</sup> Diagnostic Ultrasound System / ACUSON NX3 <sup>™</sup> Diagnostic Ultrasound System Diagnostic imaging or fluid flow analysis of the human body as follows:										
Clinical Application Other Specific (Track1 (Tracks1l& 3) Only)		Mod	e of Op	eration									
		В	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)				
Ophthalmic	Ophthalmic												
	Fetal	Р	Ρ	Р		Р	Ρ	Р					
	Abdominal	Ρ	Ρ	Р		Р	Р	Р					
	Intra-operative (Note 2)												
	Intra-operative (Neuro)												
	Laparoscopic												
Fetal	Pediatric												
Imaging & Other	SmallOrgan (Note 1)												
	Neonatal Cephalic												
	Adult Cephalic												
	Trans-rectal												
	Trans-vaginal												
	Trans-urethral												
	Trans-esoph. (non-Card.)												
	Musculo-skel. (Convent.)												
	Musculo-skel. (Superfic)												
	Intra-vascular												
	Other (Specify)												
	Cardiac Adult												
Cardiac	Cardiac Pediatric							1					
	Intra-vascular (Cardiac)												
	Trans-esophageal (Cardiac)												
	Intra-cardiac							┟────┤					
	Other (Specify)	<u> </u>						<u> </u>					
Peripheral	Peripheral vessel	<b></b>											
Vessel	Other (Specify) ation; P = previously cle												

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

Note 2

For example: abdominal, vascular Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M Note 3

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510(k) Number (if known):

C8-5 Transducer for use with: ACUSON NX3 Elite<sup>™</sup> Diagnostic Ultrasound System

Device Name: Intended Use:

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

Clinical Appli	Clinical Application			peration					
Other ( Track1 Only)	Specific (Tracks1l& 3)	в	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal	Р	Ρ	Р		Ρ	Р	Р	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric	Р	Р	Р		Р	Р	Р	
Imaging & Other	SmallOrgan (Note 1)								
	Neonatal Cephalic	Р	Р	Р		Р	Р	Р	
	Adult Cephalic	Р	Р	Р		Р	Р	Р	
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
	Cardiac Adult								
Cardiac	Cardiac Pediatric	Р	Р	Р		Р	Р	Р	
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)						l		
Peripheral	Peripheral vessel								
Vessel	Other (Specify)								

N = new indication; P = previously cleared by (K173957)

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

Note 2

For example: abdominal, vascular Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M Note 3

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510(k) Number (if known):

P8-4 Transducer for use with: ACUSON NX3 Elite<sup>™</sup> Diagnostic Ultrasound System

Device Name: Intended Use:

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

Clinical Applic	cation	Mod	e of Op	peration					
Other ( Track1 Only)	Specific (Tracks1l& 3)	В	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal	Р	Р	Р		Р	Р	Р	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric	Р	Р	Р		Р	Р	Р	
Imaging & Other	SmallOrgan (Note 1)								
	Neonatal Cephalic	Р	Р	Р		Р	Р	Р	
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
	Cardiac Adult								
Cardiac	Cardiac Pediatric	Р	Р	Р		Р	Р	Р	
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel								
Vessel	Other (Specify)								

N = new indication; P = previously cleared by (K173957)

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

Note 2

For example: abdominal, vascular Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M Note 3

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510(k) Number (if known):

11L4 Transducer for use with: ACUSON NX3 Elite<sup>™</sup> Diagnostic Ultrasound System / ACUSON NX3<sup>™</sup> Diagnostic Ultrasound System

Device Name: Intended Use:

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

Clinical Applic	cation	Mod	e of Op	peration					
Other ( Track1 Only)	Specific (Tracks1I& 3)	в	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal	Р	Ρ	Р		Р	Р	Р	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric	Р	Р	Р		Р	Р	Р	
Imaging & Other	SmallOrgan (Note 1)	Р	Р	Р		Р	Р	Р	
	Neonatal Cephalic								
	Adult Cephalic	Р	Р	Р		Р	Р	Р	
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	Р	Р	Р		Р	Р	Р	
	Musculo-skel. (Superfic)	Р	Р	Р		Р	Р	Р	
	Intra-vascular								
	Other (Specify)								
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel	Р	Р	Р		Р	Р	Р	
Vessel	Other (Specify)								

N = new indication; P = previously cleared by (K173957)

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

Note 2 For example: abdominal, vascular

Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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510(k) Number (if known):

10MC3 Transducer for use with: ACUSON NX3 Elite<sup>™</sup> Diagnostic Ultrasound System / ACUSON NX3<sup>™</sup> Diagnostic Ultrasound System

Device Name: Intended Use:

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

Clinical Application		Mode of Operation							
Other ( Track1 Only)	Specific (Tracks1l& 3)	В	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal	Р	Ρ	Р		Ρ	Ρ	Р	
	Abdominal								
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric								
Imaging & Other	SmallOrgan (Note 1)	Р	Р	Р		Ρ	Р	Р	
	Neonatal Cephalic	Р	Р	Р		Р	Р	Р	
	Adult Cephalic								
	Trans-rectal	Р	Р	Р		Р	Р	Р	
	Trans-vaginal	Р	Р	Р		Р	Р	Р	
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel								
Vessel	Other (Specify)								

N = new indication; P = previously cleared by (K173957)

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

Note 2 For example: abdominal, vascular

Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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### **Diagnostic Ultrasound Indications for Use Form**

510(k) Number (if known):

BP10-3 Transducer for use with: ACUSON NX3 Elite<sup>™</sup> Diagnostic Ultrasound System / ACUSON NX3<sup>™</sup> Diagnostic Ultrasound System

Device Name: Intended Use:

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

Clinical Application		Mode of Operation							
Other ( Track1 Only)	Specific (Tracks1I& 3)	в	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric								
Imaging & Other	SmallOrgan (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	Р	Р	Р		Р	Р	Р	
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel								
Vessel	Other (Specify)								<u> </u>

N = new indication; P = previously cleared by (K173957)

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

Note 2 For example: abdominal, vascular

Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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### **Diagnostic Ultrasound Indications for Use Form**

510(k) Number (if known):

V5Ms Transducer for use with: ACUSON NX3 Elite<sup>™</sup> Diagnostic Ultrasound System Device Name: Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
Other ( Track1 Only)	Specific (Tracks1I& 3)	в	М	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric								
Imaging & Other	SmallOrgan (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)	Р	Ρ	Р	Р	Р	Р	Р	
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel								
Vessel	Other (Specify)								

N = new indication; P = previously cleared by (K173957)

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

Note 2

For example: abdominal, vascular Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M Note 3

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### 510(k) Summary

This summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21CFR §807.92(c)

Date prepared:	September 11, 2020 – <b>Date Updated</b> : Oct. 13, 2020
Part 1. Sponsor:	Siemens Medical Solutions USA, Inc., Ultrasound Division 22010 South East 51 <sup>St</sup> Street Issaquah, WA 98029, USA
Contact Person:	Christine Dunbar Senior Regulatory Affairs Siemens Medical Solutions USA, Inc., Ultrasound Division 685 East Middlefield Road Mountain View, California 94043 Email: Christine.dunbar@siemens.com Tel: (925) 374-2045
Part 2. Device Name:	ACUSON Sequoia Diagnostic Ultrasound System ACUSON SC2000 Diagnostic Ultrasound System ACUSON Freestyle Diagnostic Ultrasound System ACUSON S1000, S2000, S3000 Diagnostic Ultrasound Systems ACUSON P200 Diagnostic Ultrasound System ACUSON P500 Diagnostic Ultrasound System ACUSON NX3, NX3 Elite Diagnostic Ultrasound System
Common Name: Classification Name:	Diagnostic ultrasound system and transducers Ultrasonic Pulsed Doppler Imaging System, Ultrasonic Pulsed Echo Imaging System, Diagnostic Ultrasound Transducer, Diagnostic Intravascular Catheter, Picture Archiving and Communications System, Biopsy Needle Guide Kit
Classification:	Regulatory Class: II Review Category: Tier II
Classification Panel CFR Section	Radiology and Cardiology 21 CFR §892.1550, §892.1560, §892.1570, §870.1200, §892.2050, §892.1560.
Product Code	90-IYN, 90-IYO, 90-ITX, 90-OBJ, 90-LLZ, 90-OIJ

Legal Manufacturer: Siemens Medical Solutions USA, Inc., Ultrasound Division 22010 South East 51<sup>St</sup> Street Issaquah, WA 98029, USA

### Part 3. Legally Marketed Predicate Devices

The Siemens ACUSON Diagnostic Ultrasound systems as described in this Special 510(k) submission is substantially equivalent to the company's legally marketed devices as represented below:

Primary Predicate Device Name	510(k) Clearance # / Date	Product Code
ACUSON Sequoia	K201462 / June 24 <sup>th</sup> , 2020	IYN, IYO, ITX, OIJ
ACUSON SC2000	K200585 / April 22, 2020	IYN, IYO, ITX, OBJ, LLZ
ACUSON Freestyle	K200644 / April 10, 2020	IYN, IYO, OIJ, ITX
ACUSON S1000, S2000, S3000	K172162 / Aug. 16, 2017	IYN, IYO, ITX, OBJ
ACUSON P200	K191922 / Aug. 15, 2019	IYN, IYO, ITX
ACUSON P500	K163396 / Jan. 04, 2017	IYN, IYO, ITX, OBJ
ACUSON NX3, NX3 Elite	K192835 / Oct. 22, 2019	IYN, IYO, ITX
Secondary Predicate Device Name	K201130 / May 26, 2020	IYN, IYO, ITX, OIJ
ACUSON Juniper		
Reference Predicate Philips Affiniti™ Diagnostic Ultrasound System Series	K201012 / May 1, 2020	IYN, IYO, ITX, QIH

### Part 4. Device Description for Representative Device, ACUSON Sequoia:

The ACUSON Sequoia Diagnostic Ultrasound System is a multi-purpose mobile, software controlled, diagnostic ultrasound system with an on-screen display of thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to transmit and receive ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Color M Mode, Doppler Tissue Mode, Amplitude Doppler Mode, a combination of modes,

Panoramic Imaging, Contrast agent Imaging, Virtual Touch Strain Imaging, Virtual Touch – pSWE Imaging, Virtual Touch – SWE Imaging, syngo Velocity Vector Imaging, Custom Tissue Imaging, 3D/4D Volume Imaging and Harmonic Imaging on a Display.

All of the transducers and the catheter-based transducers will follow Track 3 acoustic labeling (AIUM 1004, IEC 2007, AIUM/NEMA 2004a) and remain unchanged from the currently cleared ACUSON systems.

Note: Some ACUSON Diagnostic Ultrasound configurations of components, accessories and/or software may vary from device brands and within device families. There are no modifications, additions or labeling changes to components, accessories and/or software for each device indicated.

The ACUSON Diagnostic Ultrasound systems are intended to be used by trained medical professionals at various locations where patient care, evaluation, monitoring or research is performed.

### Part 5. Intended Use and Indications for Use Statements:

### K202683

### **ACUSON Sequoia Diagnostic Ultrasound System**

Indications for Use:

The ACUSON Sequoia ultrasound imaging system is intended to provide images of, or signals from, inside the body by an appropriately trained healthcare professional in a clinical setting for the following applications: Fetal, Abdominal, Pediatric, Neonatal Cephalic, Small Parts, OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures), Cardiac, Pelvic, Vascular, Adult Cephalic, Musculoskeletal and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures for fetal, abdominal, pediatric, small organ, cardiac, transrectal, transvaginal, peripheral vessel, musculoskeletal and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

### K202683

### **ACUSON SC2000 Diagnostic Ultrasound System**

Indications for Use:

The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transesophageal, Adult Cephalic, Peripheral Vessel, Abdominal, Intraoperative Abdominal, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications. The system also provides the ability to measure anatomical structures and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

The typical examinations performed using the SC2000 Ultrasound System are:

Cardiac Imaging Applications and Analysis

The system transmits ultrasound energy into adult, pediatric, neonatal, and fetal cardiac patients creating 2D (B), 3D, MMode (M), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave (PW) Doppler, and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the

Siemens Medical Solutions USA, Inc. Ultrasound Division

heail, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system also supports catheters which are intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures. The system has Cardiac

Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Vascular Imaging Applications and Analysis

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the carotid arteries or juggler veins in the neck; superficial and deep veins and arteries in the arms and legs and abdomen; and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic

capture of ultrasound images. The system has Vascular Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Superficial Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of conventional or superficial musculoskeletal structures and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

Intraoperative Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), and Pulsed Wave Doppler (PWD) to obtain images and blood flow velocity that provide guidance during intraoperative procedures.

Transcranial Imaging Applications

The system transmits ultrasound energy into the cranium of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the brain and surrounding anatomical structures to evaluate the presence or absence of pathology. The system provides Measurement Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

### K202683

### ACUSON Freestyle Diagnostic Ultrasound System

Indications for Use:

The ACUSON Freestyle Ultrasound System is intended for diagnostic imaging or fluid flow analysis of the human body performed by an appropriately trained healthcare professional in a healthcare setting for the following conditions:

Abdominal, Pediatric, Small Organ, Peripheral Vessel, Musculoskeletal (Conventional), Musculoskeletal (Superficial).

### K202683

ACUSON S1000, S2000, S3000 Diagnostic Ultrasound Systems Indications for Use:

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The ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN (including monitoring of the ovarian follicle development), Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications. The system also provides the ability to measure anatomical structures {fetal, abdominal, intraoperative, pediatric, small organ, neonatal cephalic, adult cephalic, cardiac, transesophageal, transrectal, transvaginal, peripheral vessel, musculoskeletal (conventional), musculoskeletal (superficial) and neonatal cardiac} and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task force, Endorsed by the Society for Vascular Imaging".

The ACUSON AcuNav Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heard of adult and pediatric patients.

### K202683

### **ACUSON P200 Diagnostic Ultrasound System**

Indications for Use:

The ACUSON P200 ultrasound imaging system is intended for the following applications: Fetal, Abdominal, Pediatric, Small Parts, OB/GYN (useful for visualization of the ovaries, follicles, uterus, and other pelvic structures), Adult, Pediatric and Neonatal Cardiac, Pelvic, Neonatal Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures; fetal, abdominal, pediatric, small organ, neonatal cephalic, cardiac (adult, pediatric and neonatal), transesophageal, transrectal, transvaginal, peripheral vessel, musculoskeletal (conventional), musculoskeletal (superficial) and calculations packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

### K202683

### **ACUSON P500 Ultrasound System**

Indications for Use:

The ACUSON P500 ultrasound imaging system is intended for the following applications: Fetal, Abdominal (including liver), Pediatric, Small parts, Transcranial, OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures), Pelvic, Neonatal, Cardiac, IntraCardiac, Vascular (including Peripheral Vessel), Musculoskeletal, Superficial Musculoskeletal, and Urology applications. The system also provides the ability to measure anatomical structures fetal, abdominal, small organ, transrectal, transvaginal, cardiovascular, peripheral vessel, musculoskeletal (conventional), and musculoskeletal (superficial) and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system.

This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task force, Endorsed by the Society for Vascular Imaging". The ACUSON Acunav Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.

### K202683

# ACUSON NX3 Diagnostic Ultrasound System

### ACUSON NX3 Elite Diagnostic Ultrasound System

Indications for Use:

For ACUSON NX3

The ACUSON NX3 ultrasound imaging system is intended for the following applications: Fetal, Abdominal (including liver), Pediatric, Small Parts (Small Organ), Neonatal Cephalic, Adult Cephalic, Transcranial, OB/GYN, Pelvic, Neonatal, Cardiac, Vascular (including Peripheral Vessel), Musculoskeletal, Superficial Musculoskeletal and Urology applications. The systems also provide for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes. For ACUSON NX3 Elite

The ACUSON NX3 Elite ultrasound imaging system is intended for the following applications: Fetal, Abdominal (including liver, intra-operative), Pediatric, Small Parts (Small Organ including intra-operative), Neonatal Cephalic, Adult Cephalic, Transcranial, OB/GYN, Pelvic, Neonatal, Cardiac (including Transesophageal), Vascular (including Peripheral Vessel, intra-operative), Musculoskeletal, Superficial Musculoskeletal and Urology applications. The systems also provide for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system.

Note: This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task force, Endorsed by the Society for Vascular Medicine".

### Part 6. Technological Characteristics as compared to Predicate Device

The subject devices are substantially equivalent to the cleared primary predicate devices and employs the same fundamental scientific technology and intended use/indications for use. The Intended Use and Indications for Use are not specifically intended to be modified, however the labeling is expanded to include Lung ultrasound imaging by use of marketing materials, training materials, references to clinical literature and instructions for the user to enable the creation of ultrasound protocols called Presets.

User labeling for the subject devices have been expanded to include information about lung ultrasound imaging, based on established methods or the latest professional society guidelines, for patients with coronavirus disease 2019 (COVID-19).

ACUSON Sequeia

A comparison table as Table 2 is provided beginning on the following page:

ACUSON Sequoia							
Standard Feature	ACUSON Sequoia Diagnostic Ultrasound System K# Pending	ACUSON Sequoia Diagnostic Ultrasound System K201462	Comparison				
	(Subject Device)	(Predicate Device)					
Indications for Use	The ACUSON Sequoia ultrasound imaging system is intended to provide images of, or signals from, inside the body by an appropriately trained healthcare professional in a clinical setting for the following applications: Fetal, Abdominal, Pediatric, Neonatal Cephalic, Small Parts, OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures), Cardiac, Pelvic, Vascular, Adult Cephalic, Musculoskeletal and	The ACUSON Sequoia ultrasound imaging system is intended to provide images of, or signals from, inside the body by an appropriately trained healthcare professional in a clinical setting for the following applications: Fetal, Abdominal, Pediatric, Neonatal Cephalic, Small Parts, OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures), Cardiac, Pelvic, Vascular, Adult Cephalic, Musculoskeletal and	Identical				

### Table 2: Comparison of Technological Characteristics with the Predicate Device

	ACUSON Sequoia	ACUSON Sequoia	
	Diagnostic Ultrasound	Diagnostic Ultrasound	
Standard	System	System	Comparison
Feature		K201462	Comparison
	K# Pending		
	(Subject Device)	(Predicate Device)	
	Peripheral Vascular	Peripheral Vascular	
	applications.	applications.	
	The system also provides	The system also provides	
	the ability to measure	the ability to measure	
	anatomical structures for	anatomical structures for	
	fetal, abdominal,	fetal, abdominal,	
	pediatric, small organ,	pediatric, small organ,	
	cardiac, transrectal,	cardiac, transrectal,	
	transvaginal, peripheral	transvaginal, peripheral	
	vessel, musculoskeletal	vessel, musculoskeletal	
	and calculation packages	and calculation packages	
	that provide information	that provide information	
	to the clinician that may	to the clinician that may	
	be used adjunctively with	be used adjunctively with	
	other medical data	other medical data	
	obtained by a physician	obtained by a physician	
	for clinical diagnosis	for clinical diagnosis	
	purposes.	purposes.	
Reusable?	Yes	Yes	Identical
Duration of Use	Limited ( $\leq 24$ hours)	Limited ( $\leq$ 24 hours)	Identical
Scientific		<u>`</u>	
Technology	Ultrasound Imaging	Ultrasound Imaging	Identical
Teennorogy	Diagnostic ultrasound	Diagnostic ultrasound	
	uses high-frequency	uses high-frequency	
	(above the audible range)	(above the audible range)	
	sound waves to	sound waves to	
	produce an image of	produce an image of	
	anatomical structures	anatomical structures	
	within the body. Electrical	within the body. Electrical	
	pulses vibrate	pulses vibrate	
Operating	ceramics within a	ceramics within a	
principles	transducer to transmit the	transducer to transmit the	Identical
principies	sound waves into the	sound waves into the	
	body. Sound waves	body. Sound waves	
	travel through body tissue	travel through body tissue	
	at approximately 1,540	at approximately 1,540	
		meters per second and	
	meters per second and reflect back as	reflect back as	
	echoes to the transducer at	echoes to the transducer at	
	each point of change in	each point of change in	

#### **ACUSON Sequoia ACUSON Sequoia Diagnostic Ultrasound Diagnostic Ultrasound** Standard System System Comparison Feature K# Pending K201462 (Subject Device) (Predicate Device) density, density, tissue for tissue for example, at the example, at the border of two organs in border of two organs in the body. These return the body. These return signals provide signals provide information about the information about the acoustic properties of the acoustic properties of the tissue. The time to receive tissue. The time to receive the echo in microseconds the echo in microseconds indicates a indicates a distance into the body. distance into the body. Structures furthest from Structures furthest from the transducer surface the transducer surface require more time to require more time to signal return а signal than return а than structures closer to the structures closer to the transducer surface. The transducer surface. The strength and position of strength and position of each signal indicates a each signal indicates a point of varying intensity point of varying intensity (brightness). (brightness). The The distances and intensities distances and intensities processed processed and are and are displayed on a screen to displayed on a screen to form a two-dimensional form a two-dimensional (2D) (2D) image. image. Curved Array Transducer Curved Array Transducer Linear Array Transducer Linear Array Transducer Type of Phased Array Transducer Phased Array Transducer Previously Continuous Wave **Continuous Wave** Identical cleared Transducers Transducers Transducers Curved Array Mechanical Curved Array Mechanical **3D** Transducer **3D** Transducer Acoustic Yes Yes Identical Outputs Within Range? Previously cleared Yes Yes Identical Imaging **Modes?**

### ACUSON DIAGNOSTIC ULTRASOUND SYSTEMS UPDATE Special 510(k)

Siemens Medical Solutions USA, Inc. Ultrasound Division

Standard Feature	ACUSON Sequoia Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON Sequoia Diagnostic Ultrasound System K201462 (Predicate Device)	Comparison
Biocompatibility	ISO 10993-1	ISO 10993-1	Identical

### ACUSON SC2000

ACUSON DIAGNOSTIC ULTRASOUND SYSTEMS UPDATE
Special 510(k)

	ACUSON SC2000	ACUSON SC2000	
	Diagnostic Ultrasound	Diagnostic Ultrasound	
<b>Standard Feature</b>	System	System	Comparison
	K# Pending	K200585	-
	(Subject Device)	(Predicate Device)	
	adult, pediatric, neonatal,	adult, pediatric, neonatal,	
	and fetal cardiac patients	and fetal cardiac patients	
	creating 2D (B), 3D,	creating 2D (B), 3D,	
	MMode (M), Color	MMode (M), Color	
	Doppler (CD), Color	Doppler (CD), Color	
	Power Doppler (CPD),	Power Doppler (CPD),	
	Pulsed Wave (PW)	Pulsed Wave (PW)	
	Doppler, and Continuous	Doppler, and Continuous	
	Wave Doppler (CWD) to	Wave Doppler (CWD) to	
	obtain images and blood	obtain images and blood	
	flow velocity of the heart,	flow velocity of the heart,	
	cardiac valves, great	cardiac valves, great	
	vessels, and surrounding	vessels, and surrounding	
	anatomical structures to	anatomical structures to	
	evaluate the presence or	evaluate the presence or	
	absence of pathology. The	absence of pathology. The	
	system may be used to	system may be used to	
	acquire patient		
	electrocardiogram for	electrocardiogram for	
	synchronizing the diastolic	synchronizing the diastolic	
	and systolic capture of	and systolic capture of	
	ultrasound images.	ultrasound images.	
	The system also supports	The system also supports	
	catheters which are	catheters which are	
	intended for intra-cardiac	intended for intra-cardiac	
	and intraluminal		
		visualization of cardiac	
	and great vessel anatomy	and great vessel anatomy	
	and physiology as well as visualization of other	and physiology as well as visualization of other	
	devices in the heart of adult	devices in the heart of adult	
	and pediatric patients. The	and pediatric patients. The	
	catheter is intended for	catheter is intended for	
	imaging guidance only, not	imaging guidance only, not	
	treatment delivery, during	treatment delivery, during	
	cardiac interventional	cardiac interventional	
	percutaneous procedures.	percutaneous procedures.	
	The system has Cardiac	The system has Cardiac	
	Measurements and	Measurements and	
	Calculation Packages that	Calculation Packages that	
	provide information that	provide information that	

ACUSON DIAGNOSTIC ULTRASOUND SYSTEMS UPDATE
Special 510(k)

	ACUSON SC2000	ACUSON SC2000	
	Diagnostic Ultrasound	Diagnostic Ultrasound	
<b>Standard Feature</b>	System	System	Comparison
	K# Pending	K200585	-
	(Subject Device)	(Predicate Device)	
	may be used adjunctively	may be used adjunctively	
	with other medical data	with other medical data	
	obtained by a physician for	obtained by a physician for	
	clinical diagnosis	clinical diagnosis	
	purposes.	purposes.	
	Vascular Imaging	Vascular Imaging	
	Applications and Analysis	Applications and Analysis	
	The system transmits	The system transmits	
	ultrasound energy into	ultrasound energy into	
	various parts of the body of	various parts of the body of	
	adult patients creating 2D	adult patients creating 2D	
	(B), Color Doppler (CD),	(B), Color Doppler (CD),	
	Color Power Doppler	Color Power Doppler	
	(CPD), Pulsed Wave	(CPD), Pulsed Wave	
	Doppler (PWD), and	Doppler (PWD), and	
	Continuous Wave Doppler	Continuous Wave Doppler	
	(CWD) to obtain images	(CWD) to obtain images	
	and blood flow velocity of		
	the carotid arteries or	the carotid arteries or	
	juggler veins in the neck;	juggler veins in the neck;	
	superficial and deep veins	superficial and deep veins	
	and arteries in the arms and	and arteries in the arms and	
	legs and abdomen; and	legs and abdomen; and	
	surrounding anatomical	surrounding anatomical	
	structures to evaluate the	structures to evaluate the	
	presence or absence of	presence or absence of	
	pathology. The system	pathology. The system	
	may be used to acquire	may be used to acquire	
	patient electrocardiogram	patient electrocardiogram	
	for synchronizing the diastolic and systolic		
	diastolic and systolic capture of ultrasound	diastolic and systolic capture of ultrasound	
	images. The system has	images. The system has	
	Vascular Measurements	Vascular Measurements	
	and Calculation Packages	and Calculation Packages	
	that provide information	that provide information	
	that may be used	that may be used	
	adjunctively with other	adjunctively with other	
	medical data obtained by a	medical data obtained by a	
	physician for clinical	physician for clinical	
	diagnosis purposes.	diagnosis purposes.	

	ACUSON SC2000	ACUSON SC2000	
	Diagnostic Ultrasound	Diagnostic Ultrasound	
<b>Standard Feature</b>	System	System	Comparison
	K# Pending	K200585	
	(Subject Device)	(Predicate Device)	
	Superficial Imaging	Superficial Imaging	
	Applications	Applications	
	The system transmits	The system transmits	
	ultrasound energy into	ultrasound energy into	
	various parts of the body of	various parts of the body of	
	adult patients creating 2D	adult patients creating 2D	
	(B), Color Doppler (CD),	(B), Color Doppler (CD),	
	Color Power Doppler		
	(CPD), Pulsed Wave		
	Doppler (PWD), and	Doppler (PWD), and	
	Continuous Wave Doppler	Continuous Wave Doppler	
	(CWD) to obtain images	(CWD) to obtain images	
	and blood flow velocity of	and blood flow velocity of	
	conventional or superficial	conventional or superficial	
	musculoskeletal structures	musculoskeletal structures	
	and surrounding	and surrounding	
	anatomical structures to	anatomical structures to	
	evaluate the presence or	evaluate the presence or	
	absence of pathology. The	absence of pathology. The	
	system may be used to	system may be used to	
	acquire patient	acquire patient	
	electrocardiogram for	electrocardiogram for	
	synchronizing the diastolic	synchronizing the diastolic	
	and systolic capture of	and systolic capture of	
	ultrasound images.	ultrasound images.	
	Intraoperative Imaging	Intraoperative Imaging	
	Applications	Applications	
	The system transmits	The system transmits	
	ultrasound energy into	ultrasound energy into	
	various parts of the body of adult patients creating 2D	various parts of the body of adult patients creating 2D	
	(B), Color Doppler (CD),	(B), Color Doppler (CD),	
	Color Power Doppler	Color Power Doppler	
	(CPD), and Pulsed Wave	(CPD), and Pulsed Wave	
	Doppler (PWD) to obtain	Doppler (PWD) to obtain	
	images and blood flow	images and blood flow	
	velocity that provide	velocity that provide	
	guidance during	guidance during	
	intraoperative procedures.	intraoperative procedures.	
	Transcranial Imaging	Transcranial Imaging	
	Applications	Applications	
	Applications	Applications	

Siemens Medical Solutions USA, Inc. Ultrasound Division

Standard Feature	ACUSON SC2000 Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON SC2000 Diagnostic Ultrasound System K200585 (Predicate Device)	Comparison
	The system transmits ultrasound energy into the cranium of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the brain and surrounding anatomical structures to evaluate the presence or absence of pathology. The system provides Measurement Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.	The system transmits ultrasound energy into the cranium of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the brain and surrounding anatomical structures to evaluate the presence or absence of pathology. The system provides Measurement Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.	
Reusable?	Yes	Yes	Identical
Duration of Use	Limited ( $\leq$ 24 hours)	Limited ( $\leq$ 24 hours)	Identical
Scientific Technology	Ultrasound Imaging	Ultrasound Imaging	Identical
Operating principles	Diagnostic ultrasound uses high-frequency (above the audible range) sound waves to produce an image of anatomical structures within the body. Electrical pulses vibrate ceramics within a transducer to transmit the sound waves into the body. Sound waves travel through body tissue at approximately 1,540	anatomical structures within the body. Electrical pulses vibrate ceramics within a transducer to transmit the sound waves into the body. Sound waves travel through body tissue	Identical

	ACUSON SC2000	ACUSON SC2000	
	Diagnostic Ultrasound	Diagnostic Ultrasound	
<b>Standard Feature</b>	System	System	Comparison
	K# Pending	K200585	
	(Subject Device)	(Predicate Device)	
	meters per second and	meters per second and	
	reflect back as	reflect back as	
	echoes to the transducer at	echoes to the transducer at	
	each point of change in	each point of change in	
	tissue density, for example,	tissue density, for example,	
	at the	at the	
	border of two organs in the	border of two organs in the	
	body. These return signals	body. These return signals	
	provide information about the	provide information about the	
	acoustic properties of the	acoustic properties of the	
	tissue. The time to receive	tissue. The time to receive	
	the echo in microseconds	the echo in microseconds	
	indicates a	indicates a	
	distance into the body.		
	Structures furthest from		
	the transducer surface	the transducer surface	
	require more time to return	require more time to return	
	a signal than structures	a signal than structures	
	closer to the transducer	closer to the transducer	
	surface. The strength and	surface. The strength and	
	position of each signal	position of each signal	
	indicates a point of varying	indicates a point of varying	
	intensity (brightness). The	intensity (brightness). The	
	distances and intensities	distances and intensities	
	are processed and	are processed and	
	displayed on a screen to	1 0	
	form a two-dimensional	form a two-dimensional	
	(2D)	(2D)	
	image.	image.	
	Curved Array Transducer	Curved Array Transducer	
Т С	Linear Array Transducer	Linear Array Transducer	
Type of Proviously	Phased Array Transducer	Phased Array Transducer Continuous Wave	
Previously cleared	Continuous Wave Transducers	Transducers	Identical
Transducers			
1 ransuucers	Transesophageal Transducer	Transesophageal Transducer	
	Ultrasound Catheter	Ultrasound Catheter	
Acoustic Outputs			
Within Range?	Yes	Yes	Identical
,, ium iumsu.			

Standard Feature	ACUSON SC2000 Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON SC2000 Diagnostic Ultrasound System K200585 (Predicate Device)	Comparison
Previously cleared Imaging Modes?	Yes	Yes	Identical
Biocompatibility	ISO 10993-1	ISO 10993-1	Identical

#### **ACUSON Freestyle ACUSON Freestyle Diagnostic Ultrasound Diagnostic Ultrasound Standard Feature** System System Comparison **K# Pending** K200644 (Subject Device) (Predicate Device) The ACUSON Freestyle The ACUSON Freestyle System System Ultrasound Ultrasound is is intended for diagnostic intended for diagnostic imaging or fluid flow imaging or fluid flow analysis of the human analysis of the human body performed by an body performed by an appropriately appropriately trained trained healthcare professional in healthcare professional in **Indications for** Identical a healthcare setting for the a healthcare setting for the Use following following conditions: conditions: Abdominal, Abdominal, Pediatric, Pediatric, Small Organ, Peripheral Small Organ, Peripheral Vessel. Musculoskeletal Vessel. Musculoskeletal (Conventional), (Conventional), Musculoskeletal Musculoskeletal (Superficial). (Superficial). **Reusable?** Yes Yes Identical **Duration of Use** Limited ( $\leq$ 24 hours) Limited ( $\leq 24$ hours) Identical Scientific Identical Ultrasound Imaging Ultrasound Imaging Technology Diagnostic ultrasound uses Diagnostic ultrasound uses high-frequency (above the high-frequency (above the Operating audible range) audible range) sound sound Identical principles waves to waves to produce produce image of an image of an anatomical structures anatomical structures

### **ACUSON Freestyle**

Siemens Medical Solutions USA, Inc. Ultrasound Division

	ACUSON Freestyle	ACUSON Freestyle	
	Diagnostic Ultrasound	Diagnostic Ultrasound	
<b>Standard Feature</b>	System	System	Comparison
	K# Pending	K200644	
	(Subject Device)	(Predicate Device)	
	within the body. Electrical	within the body. Electrical	
	pulses vibrate	pulses vibrate	
	ceramics within a	ceramics within a	
	transducer to transmit the	transducer to transmit the	
	sound waves into the body.	sound waves into the body.	
	Sound waves	Sound waves	
	travel through body tissue	travel through body tissue	
	at approximately 1,540	at approximately 1,540	
	meters per second and	meters per second and	
	reflect back as	reflect back as	
	echoes to the transducer at	echoes to the transducer at	
	each point of change in	each point of change in	
	tissue density, for	tissue density, for	
	example, at the	example, at the	
	border of two organs in the	border of two organs in the	
	body. These return signals	body. These return signals	
	provide information about	provide information about	
	the	the	
	acoustic properties of the	acoustic properties of the	
	tissue. The time to receive	tissue. The time to receive	
	the echo in microseconds	the echo in microseconds	
	indicates a	indicates a	
	distance into the body.	distance into the body.	
	Structures furthest from	Structures furthest from	
	the transducer surface	the transducer surface	
	require more time to return	-	
	a signal than structures	e	
	closer to the transducer	closer to the transducer	
	surface. The strength and	surface. The strength and	
	position of each signal	position of each signal	
	indicates a point of varying intensity (brightness). The	indicates a point of varying	
	intensity (brightness). The distances and intensities	intensity (brightness). The distances and intensities	
	are processed and displayed on a screen to	1	
	form a two-dimensional	displayed on a screen to form a two-dimensional	
	(2D)	(2D)	
Туре оf	image.	image.	
Previously	Curved Array Transducer	Curved Array Transducer	Identical
cleared	Linear Array Transducer	Linear Array Transducer	Inclution
cleared			

Standard Feature	ACUSON Freestyle Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON Freestyle Diagnostic Ultrasound System K200644 (Predicate Device)	Comparison
Transducers			
Acoustic Outputs Within Range?	Yes	Yes	Identical
Previously cleared Imaging Modes?	Yes	Yes	Identical
Biocompatibility	ISO 10993-1	ISO 10993-1	Identical

	ACUSON S family	ACUSON S family	
	(\$1000/\$2000/\$3000)	(S1000/S2000/S3000)	
Standard	Diagnostic Ultrasound	Diagnostic Ultrasound	Comparison
Feature	System	System	Comparison
	K# Pending	K172162	
	(Subject Device)	(Predicate Device)	
	The ultrasound imaging	The ultrasound imaging	
	systems are intended for the	systems are intended for the	
	following applications:	following applications:	
	Fetal, Abdominal,	Fetal, Abdominal,	
	Intraoperative, Pediatric,	Intraoperative, Pediatric,	
	Small Parts, Transcranial,	Small Parts, Transcranial,	
	OB/GYN (including	OB/GYN (including	
	monitoring of the ovarian	monitoring of the ovarian	
	follicle development),	follicle development),	
Indications for	Cardiac, Pelvic,	Cardiac, Pelvic,	Identical
Use	Neonatal/Adult Cephalic,	Neonatal/Adult Cephalic,	Identical
	Vascular, Musculoskeletal,	Vascular, Musculoskeletal,	
	Superficial	Superficial	
	Musculoskeletal, and	Musculoskeletal, and	
	Peripheral Vascular	Peripheral Vascular	
	applications.	applications.	
	The system also provides	The system also provides	
	the ability to measure	the ability to measure	
	anatomical structures	anatomical structures	

### **ACUSON S-Family**

	ACUSON S family	ACUSON S family	
	(S1000/S2000/S3000)	(S1000/S2000/S3000)	
Standard	Diagnostic Ultrasound	Diagnostic Ultrasound	Comparison
Feature	System	System	Comparison
	K# Pending	K172162	
	(Subject Device)	(Predicate Device)	
	{fetal, abdominal,	{fetal, abdominal,	
	intraoperative, pediatric,	intraoperative, pediatric,	
	small organ, neonatal	small organ, neonatal	
	cephalic, adult cephalic,	cephalic, adult cephalic,	
	cardiac, trans-esophageal,	cardiac, trans-esophageal,	
	transrectal, transvaginal,	transrectal, transvaginal,	
	peripheral vessel, musculo-	peripheral vessel, musculo-	
	skeletal (conventional),	skeletal (conventional),	
	musculo-skeletal	musculo-skeletal	
	(superficial) and neonatal	· · · ·	
	cardiac} and calculation	cardiac} and calculation	
	packages that provide	packages that provide	
	information to the clinician	information to the clinician	
	that may be used	that may be used	
	adjunctively with other	adjunctively with other	
	medical data obtained by a	medical data obtained by a	
	physician for clinical	physician for clinical	
	diagnosis purposes.	diagnosis purposes.	
	The Arterial Health	The Arterial Health	
	Package (AHP) software	Package (AHP) software	
	provides the physician with	provides the physician with	
	the capability to measure	the capability to measure	
	Intima Media Thickness	Intima Media Thickness	
	and the option to reference	and the option to reference	
	normative tables that have	normative tables that have	
	been validated and	been validated and	
	published in peer-reviewed	published in peer-reviewed	
	studies. The information is	studies. The information is	
	intended to provide the	intended to provide the	
	physician with an easily	physician with an easily	
	understood tool for	understood tool for	
	communicating with	communicating with	
	patients regarding state of	patients regarding state of	
	their cardiovascular	their cardiovascular	
	system. This feature should	system. This feature should	
	be utilized according to the	be utilized according to the	
	"ASE Consensus	"ASE Consensus	
	Statement; Use of Carotid	Statement; Use of Carotid	
	Ultrasound to Identify	Ultrasound to Identify	

Standard Feature	ACUSON S family (S1000/S2000/S3000) Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON S family (S1000/S2000/S3000) Diagnostic Ultrasound System K172162 (Predicate Device)	Comparison
	Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging". The ACUSON AcuNav Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.	Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging". The ACUSON AcuNav Ultrasound Catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, as well as visualization of other devices in the heart of adult and pediatric patients.	
Reusable?	Yes	Yes	Identical
Duration of Use	Limited ( $\leq$ 24 hours)	Limited ( $\leq$ 24 hours)	Identical
Scientific Technology	Ultrasound Imaging	Ultrasound Imaging	Identical
<b>Operating</b> principles	Diagnostic ultrasound uses high-frequency (above the audible range) sound waves to produce an image of anatomical structures within the body. Electrical pulses vibrate ceramics within a transducer to transmit the sound waves into the body. Sound waves travel through body tissue at approximately 1,540	Diagnostic ultrasound uses high-frequency (above the audible range) sound waves to produce an image of anatomical structures within the body. Electrical pulses vibrate ceramics within a transducer to transmit the sound waves into the body. Sound waves travel through body tissue at approximately 1,540	Identical

	ACUSON S family	ACUSON S family	
	(S1000/S2000/S3000)	(S1000/S2000/S3000)	
Standard	Diagnostic Ultrasound	Diagnostic Ultrasound	~ .
Feature	System	System	Comparison
	K# Pending	K172162	
	(Subject Device)	(Predicate Device)	
	meters per second and	meters per second and	
	reflect back as	reflect back as	
	echoes to the transducer at	echoes to the transducer at	
	each point of change in	each point of change in	
	tissue density, for example,	tissue density, for example,	
	at the	at the	
	border of two organs in the	border of two organs in the	
	body. These return signals	body. These return signals	
	provide information about	provide information about	
	the	the	
	acoustic properties of the	acoustic properties of the	
	tissue. The time to receive	tissue. The time to receive	
	the echo in microseconds	the echo in microseconds	
	indicates a	indicates a	
	distance into the body.	distance into the body.	
	Structures furthest from the	Structures furthest from the	
	transducer surface require	transducer surface require	
	more time to return a signal	more time to return a signal	
	than structures closer to the	than structures closer to the	
	transducer surface. The	transducer surface. The	
	strength and position of	strength and position of	
	each signal indicates a	each signal indicates a	
	point of varying intensity	point of varying intensity	
	(brightness). The distances	(brightness). The distances	
	and intensities are	and intensities are	
	processed and displayed on		
	a screen to form a two-	a screen to form a two-	
	dimensional (2D)	dimensional (2D)	
	image.	image.	
	Curved Array Transducer	Curved Array Transducer	
	Linear Array Transducer	Linear Array Transducer	
	Phased Array Transducer	Phased Array Transducer	
Type of	Continuous Wave	Continuous Wave	
Previously	Transducers	Transducers	Identical
cleared	Curved Array Mechanical	Curved Array Mechanical	iuciiticai
Transducers	3D Transducer	3D Transducer	
	Transesophageal	Transesophageal	
	Transducer	Transducer	
	Ultrasound Catheter	Ultrasound Catheter	
<b>Acoustic Outputs</b>	Yes	Yes	Identical

Standard Feature	ACUSON S family (S1000/S2000/S3000) Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON S family (S1000/S2000/S3000) Diagnostic Ultrasound System K172162 (Predicate Device)	Comparison
Within Range?			
Previously			
cleared	Yes	Yes	Identical
<b>Imaging Modes?</b>			
Biocompatibility	ISO 10993-1	ISO 10993-1	Identical

	ACUSON P200	ACUSON P200	
	Diagnostic Ultrasound	Diagnostic Ultrasound	
<b>Standard Feature</b>	System	System	Comparison
	K# Pending	K191922	
	(Subject Device)	(Predicate Device)	
	The ACUSON P200 ultrasound imaging system is intended for the following applications: Fetal, Abdominal, Padiatria Small Parts	is intended for the following applications: Fetal, Abdominal,	
Indications for Use	OB/GYN (useful for visualization of the ovaries, follicles, uterus, and other pelvic structures), Adult, Pediatric and Neonatal	visualization of the ovaries, follicles, uterus, and other pelvic structures), Adult, Pediatric and Neonatal Cardiac, Pelvic, Neonatal Cephalic, Vascular, Musculoskeletal, Superficial	Identical

### ACUSON P200

	ACUSON P200	ACUSON P200	
	Diagnostic Ultrasound	Diagnostic Ultrasound	
<b>Standard Feature</b>	System	System	Comparison
	K# Pending	<b>K</b> 191922	_
	(Subject Device)	(Predicate Device)	
	Peripheral Vascular	Peripheral Vascular	
	applications.	applications.	
	11	11	
	The system also provides	The system also provides	
	the ability to measure	the ability to measure	
	anatomical structures;	anatomical structures;	
	fetal, abdominal, pediatric,	fetal, abdominal, pediatric,	
	small organ, neonatal	small organ, neonatal	
	cephalic, cardiac (adult,	cephalic, cardiac (adult,	
	pediatric and neonatal),	pediatric and neonatal),	
	trans-esophageal,	trans-esophageal,	
	transrectal, transvaginal,	transrectal, transvaginal,	
	peripheral vessel,	peripheral vessel,	
	musculoskeletal	musculoskeletal	
	(conventional),	(conventional),	
	musculoskeletal	musculoskeletal	
	(superficial) and	(superficial) and	
	calculation packages that	calculation packages that	
	provide information to the	provide information to the	
	clinician that may be used	clinician that may be used	
	adjunctively with other	adjunctively with other	
	medical data obtained by a	medical data obtained by a	
	physician for clinical	physician for clinical	
	diagnosis purposes.	diagnosis purposes.	
Reusable?	Yes	Yes	Identical
<b>Duration of Use</b>	Limited ( $\leq$ 24 hours)	Limited ( $\leq$ 24 hours)	Identical
Scientific	Ultrasound Imaging	Ultrasound Imaging	Identical
Technology	Offrasound imaging	Offrasound imaging	Identical
	Diagnostic ultrasound uses	Diagnostic ultrasound uses	
	high-frequency (above the	high-frequency (above the	
	audible range) sound	audible range) sound	
	waves to	waves to	
	produce an image of	produce an image of	
Operating	anatomical structures	anatomical structures	Identical
principles	within the body. Electrical	within the body. Electrical	iuciiiicai
	pulses vibrate	pulses vibrate	
	ceramics within a	ceramics within a	
	transducer to transmit the	transducer to transmit the	
	sound waves into the body.	sound waves into the body.	
	Sound waves	Sound waves	

	ACUSON P200	ACUSON P200	
	Diagnostic Ultrasound	Diagnostic Ultrasound	
Standard Feature	System	System	Comparison
	K# Pending	K191922	e omparison
	(Subject Device)	(Predicate Device)	
	travel through body tissue	travel through body tissue	
	at approximately 1,540	at approximately 1,540	
	meters per second and	meters per second and	
	reflect back as	reflect back as	
	echoes to the transducer at		
	each point of change in		
	tissue density, for	tissue density, for	
	example, at the	example, at the	
	border of two organs in the	border of two organs in the	
	body. These return signals	body. These return signals	
	provide information about	provide information about	
	the	the	
	acoustic properties of the	acoustic properties of the	
	tissue. The time to receive	tissue. The time to receive	
	the echo in microseconds	the echo in microseconds	
	indicates a	indicates a	
	distance into the body.	distance into the body.	
	Structures furthest from	Structures furthest from	
	the transducer surface	the transducer surface	
	require more time to return	require more time to return	
	a signal than structures	a signal than structures	
	closer to the transducer	closer to the transducer	
	surface. The strength and	surface. The strength and	
	position of each signal	position of each signal	
	indicates a point of varying	indicates a point of varying	
	intensity (brightness). The	intensity (brightness). The	
	distances and intensities	distances and intensities	
	are processed and	are processed and	
	displayed on a screen to	displayed on a screen to	
	form a two-dimensional	form a two-dimensional	
	(2D)	(2D)	
	image.	image.	
	Curved Array Transducer	Curved Array Transducer	
Type of	Linear Array Transducer	Linear Array Transducer	
Previously	Phased Array Transducer	Phased Array Transducer	
cleared	Continuous Wave	Continuous Wave	Identical
Transducers	Transducers	Transducers	
11 ansuutti s	Transesophageal	Transesophageal	
	Transducer	Transducer	
Acoustic Outputs	Yes	Yes	Identical
Within Range?	100	100	identioui

Standard Feature	ACUSON P200 Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON P200 Diagnostic Ultrasound System K191922 (Predicate Device)	Comparison
Previously cleared Imaging Modes?	Yes	Yes	Identical
Biocompatibility	ISO 10993-1	ISO 10993-1	Identical

## ACUSON P500

Standard Feature	ACUSON P500 Ultrasound System K# Pending (Subject Device)	ACUSON P500 Ultrasound System K163396 (Predicate Device)	Comparison
Indications for Use	The ACUSON P500 ultrasound imaging system is intended for the following applications: Fetal, Abdominal (including liver), Pediatric, Small Parts, Transcranial, OB/GYN(useful for visualization of ovaries, follicles, uterus and other pelvic structures), Pelvic, Neonatal, Cardiac, IntraCardiac, Vascular(including Peripheral Vessel), Musculoskeletal, Superficial Musculoskeletal, and Urology applications. The system also provides the ability to measure anatomical structures fetal, abdominal, small organ, transrectal, transvaginal, cardiovascular, peripheral vessel, musculoskeletal (conventional), and	The ACUSON P500 ultrasound imaging system is intended for the following applications: Fetal, Abdominal (including liver), Pediatric, Small Parts, Transcranial, OB/GYN(useful for visualization of ovaries, follicles, uterus and other pelvic structures), Pelvic, Neonatal, Cardiac, IntraCardiac, Vascular(including Peripheral Vessel), Musculoskeletal, Superficial Musculoskeletal, and Urology applications. The system also provides the ability to measure anatomical structures fetal, abdominal, small organ, transrectal, transvaginal, cardiovascular, peripheral vessel, musculoskeletal (conventional), and	Identical

	ACUSON P500	ACUSON P500	
Standard	Ultrasound System	Ultrasound System	<b>C</b>
Feature	K# Pending	K163396	Comparison
	(Subject Device)	(Predicate Device)	
	musculoskeletal	musculoskeletal	
	(superficial) and	(superficial) and	
	calculation packages that	calculation packages that	
	provide information to the	provide information to the	
	clinician that may be used	clinician that may be used	
	adjunctively with other	adjunctively with other	
	medical data obtained by a	medical data obtained by a	
	physician for clinical	physician for clinical	
	diagnosis purposes.	diagnosis purposes.	
	The Arterial Health	The Arterial Health	
	Package (AHP) software	Package (AHP) software	
	provides the physician with	provides the physician with	
	the capability to measure	the capability to measure	
	Intima Media Thickness	Intima Media Thickness	
	and the option to reference	and the option to reference	
	normative tables that have	normative tables that have	
	been validated and	been validated and	
	published in peer-reviewed	published in peer-reviewed	
	studies. The information is	studies. The information is	
	intended to provide the physician with an easily	intended to provide the physician with an easily	
	understood tool for	understood tool for	
	communicating with	communicating with	
	patients regarding state of	patients regarding state of	
	their cardiovascular	their cardiovascular	
	system.	system.	
	This feature should be	This feature should be	
	utilized according to the	utilized according to the	
	"ASE Consensus	"ASE Consensus	
	Statement; Use of Carotid		
	Ultrasound to Identify	Ultrasound to Identify	
	Subclinical Vascular	5	
	Disease and Evaluate	Disease and Evaluate	
	Cardiovascular Disease	Cardiovascular Disease	
	Risk: A Consensus	Risk: A Consensus	
	Statement from the	Statement from the	
	American Society of	•	
	Echocardiography Carotid	Echocardiography Carotid	
	Intima-Media Thickness	Intima-Media Thickness	
	Task Force. Endorsed by	Task Force. Endorsed by	

Standard	ACUSON P500 Ultrasound System	ACUSON P500 Ultrasound System	Comparison
Feature	K# Pending (Subject Device)	K163396 (Predicate Device)	1
	the Society for Vascular		
	Imaging."	Imaging."	
	The ACUSON Acunav	The ACUSON Acunav	
	Ultrasound Catheter is		
	intended for intra-cardiac		
	and intra-luminal	and intra-luminal	
	visualization of cardiac and	visualization of cardiac and	
	great vessel anatomy and	great vessel anatomy and	
	physiology, as well as	physiology, as well as	
	visualization of other devices in the heart of adult	visualization of other devices in the heart of adult	
	and pediatric patients.	and pediatric patients.	
Reusable?	Yes	Yes	Identical
<b>Duration of Use</b>	Limited ( $\leq$ 24 hours)	Limited ( $\leq$ 24 hours)	Identical
Scientific	Ultrasound Imaging	Ultrasound Imaging	Identical
Technology			lacitical
	Diagnostic ultrasound uses high-frequency (above the	Diagnostic ultrasound uses high-frequency (above the	
	audible range) sound	audible range) sound	
	waves to	waves to	
	produce an image of	produce an image of	
	anatomical structures	anatomical structures	
	within the body. Electrical	within the body. Electrical	
	pulses vibrate	pulses vibrate	
	ceramics within a transducer to transmit the		
	sound waves into the body.	sound waves into the body.	
Operating	Sound waves	Sound waves	T.1
principles	travel through body tissue	travel through body tissue	Identical
	at approximately 1,540	at approximately 1,540	
	meters per second and	meters per second and	
	reflect back as echoes to the transducer at	reflect back as echoes to the transducer at	
	each point of change in	each point of change in	
	tissue density, for example,	tissue density, for example,	
	at the	at the	
	border of two organs in the	border of two organs in the	
	body. These return signals	body. These return signals	
	provide information about	provide information about	
	the	the	

Standard Feature	ACUSON P500 Ultrasound System K# Pending (Subject Device)	ACUSON P500 Ultrasound System K163396 (Predicate Device)	Comparison
	acoustic properties of the tissue. The time to receive the echo in microseconds indicates a distance into the body. Structures furthest from the transducer surface require more time to return a signal than structures closer to the transducer surface. The strength and position of each signal indicates a point of varying intensity (brightness). The distances and intensities are processed and displayed on a screen to form a two- dimensional (2D) image.	acoustic properties of the tissue. The time to receive the echo in microseconds indicates a distance into the body. Structures furthest from the transducer surface require more time to return a signal than structures closer to the transducer surface. The strength and position of each signal indicates a point of varying intensity (brightness). The distances and intensities are processed and displayed on a screen to form a two- dimensional (2D) image.	
Type of Previously cleared Transducers	Curved Array Transducer Linear Array Transducer Phased Array Transducer Continuous Wave Transducers Ultrasound Catheter	Curved Array Transducer Linear Array Transducer Phased Array Transducer Continuous Wave Transducers Ultrasound Catheter	Identical
Acoustic Outputs Within Range?	Yes	Yes	Identical
Previously cleared Imaging Modes?	Yes	Yes	Identical
Biocompatibility	ISO 10993-1	ISO 10993-1	Identical

## ACUSON NX3/NX3 Elite

Standard Feature	ACUSON NX3/NX3 Elite Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON NX3/NX3 Elite Diagnostic Ultrasound System K192835 (Predicate Device)	Comparison
Indications for Use	ACUSON NX3	ACUSON NX3	Identical

	ACUSON NX3/NX3	ACUSON NX3/NX3	
Standard	Elite Diagnostic	Elite Diagnostic	
Feature	Ultrasound System	Ultrasound System	Comparison
reature	K# Pending	K192835	
	(Subject Device)	(Predicate Device)	
	The ACUSON NX3	The ACUSON NX3	
	ultrasound imaging system	ultrasound imaging system	
	is intended for the	is intended for the	
	following applications:	following applications:	
	Fetal Abdominal	Fetal Abdominal	
	(including liver), Pediatric,	(including liver), Pediatric,	
	Small Parts (Small Organ),	Small Parts (Small Organ),	
	Neonatal Cephalic, Adult	Neonatal Cephalic, Adult	
	Cephalic, Transcranial,	Cephalic, Transcranial,	
	OB/GYN, Pelvic, Neonatal, Cardiac,	OB/GYN, Pelvic, Neonatal, Cardiac,	
	Neonatal, Cardiac, Vascular (including	Vascular (including	
	Peripheral Vessel),	Peripheral Vessel),	
	Musculoskeletal,	Musculoskeletal,	
	Superficial	Superficial	
	Musculoskeletal and	Musculoskeletal and	
	Urology applications.	Urology applications.	
	The systems also provide	The systems also provide	
	for the measurement of	for the measurement of	
	anatomical structures and	anatomical structures and	
	for analysis packages that	for analysis packages that	
	provide information that is	provide information that is	
	used for clinical diagnosis	used for clinical diagnosis	
	purposes.	purposes.	
	ACUSON NX3 Elite	ACUSON NX3 Elite	
	The ACUSON NX3 Elite	The ACUSON NX3 Elite	
	ultrasound imaging system	ultrasound imaging system	
	is intended for the	is intended for the	
	following applications:	following applications:	
	Fetal, Abdominal	Fetal, Abdominal	
	(including liver, intra-	(including liver, intra-	
	operative), Pediatric, Small	operative), Pediatric, Small	
	Parts (Small Organ	Parts (Small Organ	
	including intra-operative),	including intra-operative),	
	Neonatal Cephalic, Adult	Neonatal Cephalic, Adult	
	Cephalic, Transcranial,	Cephalic, Transcranial,	
	OB/GYN, Pelvic,	OB/GYN, Pelvic,	
	Neonatal, Cardiac,	Neonatal, Cardiac,	
	Vascular (including	Vascular (including	

Standard Feature	ACUSON NX3/NX3 Elite Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON NX3/NX3 Elite Diagnostic Ultrasound System K192835 (Predicate Device)	Comparison
	Peripheral Vessel, intra- operative), Musculoskeletal, Superficial Musculoskeletal and Urology applications.	Peripheral Vessel, intra- operative), Musculoskeletal, Superficial Musculoskeletal and Urology applications.	
	The systems also provide for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.	The systems also provide for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.	
	The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system.	The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system.	
	Note: This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease	Note: This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease	

	ACUSON NX3/NX3	ACUSON NX3/NX3	
Standard	Elite Diagnostic	Elite Diagnostic	
Feature	Ultrasound System	Ultrasound System	Comparison
I Catul C	K# Pending	K192835	
	(Subject Device)	(Predicate Device)	
	Risk: A Consensus	Risk: A Consensus	
	Statement from the American Society of	Statement from the American Society of	
	American Society of Echocardiography; Carotid	American Society of Echocardiography; Carotid	
	Intima-Media Thickness	Intima-Media Thickness	
	Task Force, Endorsed by	Task Force, Endorsed by	
	the Society for Vascular	the Society for Vascular	
	Medicine.".	Medicine.".	
Reusable?	Yes	Yes	Identical
<b>Duration of Use</b>	Limited ( $\leq$ 24 hours)	Limited ( $\leq$ 24 hours)	Identical
Scientific Technology	Ultrasound Imaging	Ultrasound Imaging	Identical
Operating principles	Diagnostic ultrasound uses high-frequency (above the audible range) sound waves to produce an image of anatomical structures within the body. Electrical pulses vibrate ceramics within a transducer to transmit the sound waves into the body. Sound waves travel through body tissue at approximately 1,540 meters per second and reflect back as echoes to the transducer at each point of change in tissue density, for example, at the border of two organs in the body. These return signals provide information about the acoustic properties of the tissue. The time to receive the echo in microseconds indicates a	Diagnostic ultrasound uses high-frequency (above the audible range) sound waves to produce an image of anatomical structures within the body. Electrical pulses vibrate ceramics within a transducer to transmit the sound waves into the body. Sound waves travel through body tissue at approximately 1,540 meters per second and reflect back as echoes to the transducer at each point of change in tissue density, for example, at the border of two organs in the body. These return signals provide information about the acoustic properties of the tissue. The time to receive the echo in microseconds indicates a	Identical

	ACUSON NX3/NX3	ACUSON NX3/NX3	
	Elite Diagnostic	Elite Diagnostic	
Standard	Ultrasound System	Ultrasound System	Comparison
Feature	K# Pending	K192835	<u> </u>
	(Subject Device)	(Predicate Device)	
	distance into the body.	distance into the body.	
	Structures furthest from the	Structures furthest from the	
	transducer surface require	transducer surface require	
	more time to return a signal	more time to return a signal	
	than structures closer to the	than structures closer to the	
	transducer surface. The	transducer surface. The	
	strength and position of	strength and position of	
	each signal indicates a	each signal indicates a	
	point of varying intensity	point of varying intensity	
	(brightness). The distances	(brightness). The distances	
	and intensities are	and intensities are	
	processed and displayed on	processed and displayed on	
	a screen to form a two-	a screen to form a two-	
	dimensional (2D)	dimensional (2D)	
	image.	image.	
	NX3	NX3	
	Curved Array Transducer	Curved Array Transducer	
	Linear Array Transducer	Linear Array Transducer	
	Phased Array Transducer	Phased Array Transducer	
	Curved Array Mechanical 3D Transducer	Curved Array Mechanical 3D Transducer	
	3D Transducer	3D Transducer	
Type of	NX3 Elite	NX3 Elite	
Previously	Curved Array Transducer	Curved Array Transducer	Identical
cleared	Linear Array Transducer	Linear Array Transducer	
Transducers	Phased Array Transducer	Phased Array Transducer	
	Continuous Wave	Continuous Wave	
	Transducers	Transducers	
	Curved Array Mechanical	Curved Array Mechanical	
	3D Transducer	3D Transducer	
	Transesophageal	Transesophageal	
	Transducer	Transducer	
Acoustic Outputs	Yes	Yes	Identical
Within Range?			
Previously	X7	<b>X</b> 7	<b>T1</b> . 1
cleared	Yes	Yes	Identical
Imaging Modes?		100 10002 1	T 1 1
Biocompatibility	ISO 10993-1	ISO 10993-1	Identical

### Substantial Equivalence Conclusion:

From the information provided in Table 2 above; it is understood that the subject device does not introduce any new fundamental technology or modify the indications of use; therefore, the listed ACUSON Diagnostic Ultrasound systems as listed in Table 2 are considered substantially equivalent to their individual predicate devices including the expanded labeling.

# Part 7. A brief discussion of nonclinical testing submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence.

The Customer Requirement Specifications (CRS) for each listed ACUSON Diagnostic Ultrasound device was verified and validated according to the design control requirements of 21 CFR 820.30 during the original project development of the predicate version of each device and remain unchanged from their currently cleared configuration. Each predicate version of the listed device has been subjected to extensive safety and requirements verification testing before release to ensure the device meets all its specifications including conformance to the following standards:

- IEC 62304:2006/A1:2016 Medical Device Software Software Life Cycle Processes
- IEC 62366-1:2015, Application of usability engineering to medical devices.
- NEMA PS 3.1 3.20 (2016), Digital Imaging and Communications in Medicine (DICOM set).

The testing results for each listed ACUSON Diagnostic Ultrasound System to support the claim of conformity are available upon request. There are no software or hardware modifications to any device under this review and the expanded labeling has no impact on the individual ACUSON ultrasound device, therefore, testing results are not included in this Special 510(k) submission.

For the expanded Labeling for each ACUSON Diagnostic Ultrasound Device as listed above, the use of currently cleared customizable PreSets will be supported by availability of the Educational materials and current literature currently posted on the Siemens Healthineers website and included in this submission under Labeling.

### Software Verification and Validation

In accordance with the FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005, documentation is included within this submission for software of a Moderate Level of Concern. Non-clinical Testing has been conducted during product development for each of the predicate ACUSON Diagnostic Ultrasound device described in this submission.

The expanded Labeling for customer use of educational and training materials specifically for Lung Ultrasound imaging does not impact the software for any listed device.

Cybersecurity considerations related to the ACUSON Diagnostic Ultrasound systems device software has been address within each product. Siemens conforms to cybersecurity requirements by implementing a means to prevent unauthorized access, modification, misuse, denial of use or unauthorized use of information stored, accessed or transferred from a medical device to an external recipient.

A risk analysis, in compliance with ISO 14971:2007, for each of the ACUSON Diagnostic Ultrasound systems device during their development of the predicate devices was conducted and mitigation controls were implemented for identified hazards. Verification and validation testing confirm that all software specifications have been implemented on the respective predicate devices and met the defined acceptance criteria. The predicate devices remain unchanged from their currently cleared software version, configuration and accessories.

Note: Risk analysis was performed by the Risk management team by review of clinical literature.

# Part 8. A summary discussion of the clinical tests submitted, referenced, or relied on for a determination of substantial equivalence.

The ACUSON Diagnostic Ultrasound systems device are all FDA Class II devices and uses the same technology and operating principles as their respective predicate devices, therefore clinical studies were not required to support substantial equivalence. The expanded Labeling for Lung Ultrasound imaging (LUS) is supported by clinical literature.

### Part 9. Safety and Effectiveness Information

The currently cleared Device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of each device listed. Risk management was implemented throughout the development process for each ACUSON Diagnostic Ultrasound system to control potential hazards. Siemens believes that the expanded Labeling is safe and effective for the use of instructions for Lung ultrasound imaging (LUS) and does not introduce new safety and effectiveness concerns.

### Part 10. Conclusion as to Substantial Equivalence Summary

Based on the information provided here in the summary and from the device comparison in Table 2; ACUSON Diagnostic Ultrasound systems have the same indications for use as the primary predicate devices. The device Labeling has been expanded to include information regarding the use of Ultrasound Imaging of the Lung imaging by the use of adequate descriptions necessary for training on scanning

Siemens Medical Solutions USA, Inc. Ultrasound Division

techniques for Lung imaging, description for Users to create Lung Preset settings by using the Preset Customization tools currently available on all cleared ACUSON devices indicated in this submission and referencing clinical information distributed to the clinicians various peer reviewed Journal articles.

There are no new features or software changes from the primary predicate devices and no new issues of safety or effectiveness are raised.

Siemens Medical Solutions USA, Inc, Ultrasound Business Unit considers the all of the ACUSON Diagnostic Ultrasound systems with expanded Labeling to be substantially equivalent with respect to safety and effectiveness to the previously cleared predicate devices for the U.S. market.