Siemens Medical Solutions, USA, Inc.
℅ Ms. Christine Dunbar
Senior Regulatory Affairs Specialist
22010 South East 51st Street
ISSAQUAH WA 98029

October 15, 2020

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 P500 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 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm 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 Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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 https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **ACUSON Sequoia Diagnostic Ultrasound System**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

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

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **4V1 Phased Array Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	
Abdominal		P	P	P		P	P		BMDC	
Intraoperative										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		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)

_____
Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMCD	
Abdominal		P	P	P		P	P		BMCD	
Intraoperative										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		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)

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMCD	
Abdominal		P	P	P		P	P		BMCD	
Intraoperative										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		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)

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

Diagnostic Ultrasound Indications for Use Form

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:

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

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

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

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

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

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

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **14L5 Linear Array Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **10L4 Linear Array Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

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

Clinical Application	Mode of Operation									
	A	B	M	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		P	P	P		P	P		BMCD	
Transvaginal		P	P	P		P	P		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)

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

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMCD	
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic		P	P	P		P	P		BMCD	
Cardiac		P	P	P	P	P	P		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)

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

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P	P	P		P	P		BMCD	
Intraoperative										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMCD	
Small Organ (Note 1)										
Neonatal Cephalic		P	P	P		P	P		BMCD	
Adult Cephalic										
Cardiac		P	P	P	P	P	P		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)

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

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric					P					
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					P					
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)

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

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **10V4 Phased Array Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMCD	
Small Organ (Note 1)										
Neonatal Cephalic		P	P	P		P	P		BMCD	
Adult Cephalic										
Cardiac		P	P	P	P	P	P		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)

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

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **18H6 Linear Array Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **CW5 Continuous Wave Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	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					P					
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)

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

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **7L2 Linear Array Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P	P	P		P	P		BMCD	
Intraoperative										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMCD	
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		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)

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

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **11M3 Curved Array Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMCD	
Small Organ (Note 1)										
Neonatal Cephalic		P	P	P		P	P		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)

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

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation									
	A	B	M	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		N	N	N		N	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)

_____

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Indications for Use

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

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **ACUSON Freestyle™ Diagnostic Ultrasound System**

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

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

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **L8-3 Linear Array Transducer**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

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

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **L13-5 Linear Array Transducer**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

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

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **L17-5 Linear Array Transducer**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify) **(Note 2)**	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		N				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		N				N	N			
Laparoscopic										
Musculo-skeletal Conventional		N				N	N			
Musculo-skeletal Superficial		N				N	N			
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)

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

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **C5-2 Curvilinear Array Transducer**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____

Device Name: **ACUSON S1000, S2000 and S3000 Ultrasound Systems**

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

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

_____

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

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

_____

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

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

_____

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	
Abdominal		P	P	P		P	P		BMDC	
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ		P	P	P		P	P		BMDC	Note 1
Neonatal Cephalic		P	P	P		P	P		BMDC	
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal		P	P	P		P	P		BMDC	
Transvaginal		P	P	P		P	P		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)

_____

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	
Abdominal		P	P	P		P	P		BMDC	
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ		P	P	P		P	P		BMDC	Note 1
Neonatal Cephalic		P	P	P		P	P		BMDC	
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal		P	P	P		P	P		BMDC	
Transvaginal		P	P	P		P	P		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)

_____

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

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

_____

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

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

_____

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	
Abdominal		P	P	P	P	P	P		BMDC	
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic		P	P	P	P	P	P		BMDC	
Cardiac		P	P	P	P	P	P		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)

_____

Concurrence of Center for Devices and Radiological Health(CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	
Abdominal		P	P	P		P	P		BMDC	
Intraoperative										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		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)

_____

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	
Abdominal		P	P	P	P	P	P		BMDC	
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ		P	P	P	P	P	P		BMDC	Note 2
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		BMDC	
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		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)

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

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	
Abdominal		P	P	P	P	P	P		BMDC	
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ		P	P	P	P	P	P		BMDC	Note 2
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		BMDC	
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		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)

_____

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	
Abdominal		P	P	P		P	P		BMDC	
Intraoperative										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	
Small Organ		P	P	P		P	P		BMDC	Note 2
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		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)

_____

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	
Abdominal		P	P	P		P	P		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)

_____

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	
Abdominal		P	P	P	P	P	P		BMDC	
Intraoperative										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	
Small Organ										
Neonatal Cephalic		P	P	P	P	P	P		BMDC	
Adult Cephalic										
Cardiac		P	P	P	P	P	P		BMDC	
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		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)

_____

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative		P	P	P		P	P		BMDC	Note 2
Intraoperative Neurological										
Pediatric										
Small Organ		P	P	P		P	P		BMDC	Note 1
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P		P	P		BMDC	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		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)

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	
Abdominal		P	P	P		P	P		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)

_____

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	
Abdominal		P	P	P		P	P		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)

_____

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic		P	P	P		P	P		BMDC	
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal		P	P	P		P	P		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)

_____

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation									
	A	B	M	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		P	P	P	P	P	P		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)

_____

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

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

_____

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

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

_____

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

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

_____

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	
Abdominal		P	P	P	P	P	P		BMDC	
Intraoperative										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal		P	P	P	P	P	P		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)

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify) *	Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal											
Abdominal		P	P	P	P	P	P		P	P	
Intraoperative											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P	P	
Small Organ											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P	P	
Trans-esophageal		P	P	P	P	P	P		P	P	
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: 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

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

_____

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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™ 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.

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

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

Additional Comments:

*Combinations include: 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

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

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™ 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	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify) *	Other: Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Vascular)										
Intraoperative (Neurological)										
Pediatric		P	P	P	P	P	P		P	
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P	
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal		P	P	P	P	P	P		P	
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Intra-Cardiac)		P	P	P	P	P	P		P	

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

Additional Comments:

*Combinations include: 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

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

Concurrence of Center for Devices and Radiological Health (CDRH)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

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 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Diagnostic Ultrasound Indications for Use Form

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:

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

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

Note 1 For example: Breast, Thyroid, Testis
Note 2 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)

_____

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **4V1 Phased Array Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Fetal	P	P	P		P	P	BMDC	
Abdominal	P	P	P		P	P	BMDC	
Intraoperative								
Intraoperative Neurological								
Pediatric	P	P	P		P	P	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

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

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

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

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

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative								
Intraoperative Neurological								
Pediatric	P	P	P	P	P	P	BMCD	
Small Organ (Note 1)								
Neonatal Cephalic								
Adult Cephalic								
Cardiac	P	P	P	P	P	P	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 For example: Breast, Thyroid, Testis
Note 2 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)

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

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Fetal								
Abdominal	P	P	P		P	P	BMCD	
Intraoperative								
Intraoperative Neurological								
Pediatric	P	P	P	P	P	P	BMCD	
Small Organ (Note 1)								
Neonatal Cephalic								
Adult Cephalic								
Cardiac	P	P	P	P	P	P	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 For example: Breast, Thyroid, Testis
Note 2 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)

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

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Fetal								
Abdominal	P	P	P		P	P	BMCD	
Intraoperative								
Intraoperative Neurological								
Pediatric	P	P	P		P	P	BMCD	
Small Organ (Note 1)								
Neonatal Cephalic	P	P	P		P	P	BMCD	
Adult Cephalic								
Cardiac	P	P	P	P	P	P	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
Note 2 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)

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

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative								
Intraoperative Neurological								
Pediatric				P				
Small Organ (Note 1)								
Neonatal Cephalic								
Adult Cephalic								
Cardiac				P				
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
Note 2 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)

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

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **CW5 Continuous Wave Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Fetal								
Abdominal								
Intraoperative								
Intraoperative Neurological								
Pediatric				P				
Small Organ (Note 1)								
Neonatal Cephalic								
Adult Cephalic								
Cardiac								
Trans-esophageal								
Transrectal								
Transvaginal								
Transurethral								
Intravascular								
Peripheral vessel (Note 2)				P				
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
Note 2 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)

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

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **10L4 Linear Array Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **14L5 Linear Array Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

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

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

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

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

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

Diagnostic Ultrasound Indications for Use Form

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:

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Fetal	P	P	P		P	P	BMCD	
Abdominal	P	P	P		P	P	BMCD	
Intraoperative								
Intraoperative Neurological								
Pediatric	P	P	P		P	P	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 For example: Breast, Thyroid, Testis
Note 2 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)

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

Diagnostic Ultrasound Indications for Use Form

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:

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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

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

Clinical Application	Mode of Operation							
	B	M	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	P	P	P		P	P	BMCD	
Transvaginal	P	P	P		P	P	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 For example: Breast, Thyroid, Testis
Note 2 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)

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

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **V5Ms Multiplane TEE Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	B	M	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	P	P	P	P	P	P	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 For example: Breast, Thyroid, Testis
Note 2 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)

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **ACUSON P500™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	BMDC	Note 2, 3, 4, 11, 12, 16
	Abdominal	P	P	P	P	P	P	BMDC	Note 2, 3, 4, 11, 12, 16
	Intra-operative (Note 6)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)	P	P	P		P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16
	Neonatal Cephalic				N				
	Adult Cephalic				N				
	Trans-rectal	P	P	P		P	P	BMDC	Note 2, 3, 4, 11, 12, 16
	Trans-vaginal	P	P	P		P	P	BMDC	Note 2, 3, 4, 11, 12, 16
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	P	P	P		P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16
	Musculo-skel. (Superfic)	P	P	P		P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16
	Intra -vascular								
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	BMDC	Note 2, 4, 6, 7, 8, 10, 12, 16
	Cardiac Pediatric	N	N	N	N	N	N	BMDC	Note 2, 4, 6, 7, 10, 12, 16
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-Cardiac	N	N	N	N	N	N	BMDC	Note 2, 4, 10, 12, 14, 15, 16
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P	N	P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16
	Other (Specify)								

N = new indication; P = previously cleared

Note 1	For example: breast, testes, thyroid, prostate, etc.
Note 2	Dynamic TCE Technology
Note 3	Advanced SieClear
Note 4	eSieImage
Note 5	For example: abdominal, vascular (upper and lower)
Note 6	Stress Echo
Note 7	eSieMeasure
Note 8	eSieScan
Note 9	AHP
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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **P4-2** Phased Array Transducer for use with:
ACUSON P500™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	BMDC	Note 2, 4, 12,16
	Abdominal	P	P	P	P	P	P	BMDC	Note 2, 4, 12,16
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	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	Cardiac Adult	P	P	P	P	P	P	BMDC	Note 2, 4, 6, 7, 8, 10, 12, 16
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel (Note 5)								
	Other (Specify)								

N = new indication; P = previously cleared K150050

Note 1	For example: breast, testes, thyroid, prostate, etc.
Note 2	Dynamic TCE Technology
Note 3	Advanced SieClear
Note 4	eSieImage
Note 5	For example: abdominal, vascular (upper and lower)
Note 6	Stress Echo
Note 7	eSieMeasure
Note 8	eSieScan
Note 9	AHP
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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **CH5-2** Curved Array Transducer for use with:
ACUSON P500™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	BMDC	Note 2, 3, 4, 11, 12, 16
	Abdominal	P	P	P		P	P	BMDC	Note 2, 3, 4, 11, 12, 16
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	P	P	P		P	P	BMDC	Note 2, 3, 4, 11, 12, 16
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel (Note 5)	P	P	P		P	P	BMDC	Note 2, 3, 4, 11, 12, 16
	Other (Specify)								

N = new indication; P = previously cleared K150050

Note 1	For example: breast, testes, thyroid, prostate, etc.
Note 2	Dynamic TCE Technology
Note 3	Advanced SieClear
Note 4	eSieImage
Note 5	For example: abdominal, vascular (upper and lower)
Note 6	Stress Echo
Note 7	eSieMeasure
Note 8	eSieScan
Note 9	AHP
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

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

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

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

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **VF10-5** Linear Array Transducer for use with: **ACUSON P500™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)	P	P	P		P	P	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.)	P	P	P		P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel (Note 5)	P	P	P		P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16
	Other (Specify)								

N = new indication; P = previously cleared K150050

Note 1	For example: breast, testes, thyroid, prostate, etc.
Note 2	Dynamic TCE Technology
Note 3	Advanced SieClear
Note 4	eSieImage
Note 5	For example: abdominal, vascular (upper and lower)
Note 6	Stress Echo
Note 7	eSieMeasure
Note 8	eSieScan
Note 9	AHP
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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **EC9-4** Curved Array Transducer for use with:
ACUSON P500™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	BMDC	Note 2, 3, 4, 11, 12, 16
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)	P	P	P		P	P	BMDC	Note 2, 3, 4, 11, 12, 16
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	BMDC	Note 2, 3, 4, 11, 12, 16
	Trans-vaginal	P	P	P		P	P	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	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel (Note 5)								
	Other (Specify)								

N = new indication; P = previously cleared K150050

Note 1	For example: breast, testes, thyroid, prostate, etc.
Note 2	Dynamic TCE Technology
Note 3	Advanced SieClear
Note 4	eSieImage
Note 5	For example: abdominal, vascular (upper and lower)
Note 6	Stress Echo
Note 7	eSieMeasure
Note 8	eSieScan
Note 9	AHP
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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **VF13-5** Linear Transducer for use with:
ACUSON P500™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)	P	P	P		P	P	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)	P	P	P		P	P	BMDC	Note 2, 3, 4 , 9, 11, 12, 13, 16
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel (Note 5)	P	P	P		P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16
	Other (Specify)								

N = new indication; P = previously cleared K150050

Note 1	For example: breast, testes, thyroid, prostate, etc.
Note 2	Dynamic TCE Technology
Note 3	Advanced SieClear
Note 4	eSieImage
Note 5	For example: abdominal, vascular (upper and lower)

Note 6	Stress Echo
Note 7	eSieMeasure
Note 8	eSieScan
Note 9	AHP
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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: VF16-5 Transducer for use with:
ACUSON P500™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)	P	P	P		P	P	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)	P	P	P		P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel (Note 5)								
	Other (Specify)								

N = new indication; P = previously cleared K141846

Note 1	For example: breast, testes, thyroid, prostate, etc.
Note 2	Dynamic TCE Technology
Note 3	Advanced SieClear
Note 4	eSieImage
Note 5	For example: abdominal, vascular (upper and lower)
Note 6	Stress Echo
Note 7	eSieMeasure
Note 8	eSieScan
Note 9	AHP
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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: P8-4 Transducer for use with:
ACUSON P500™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	BMDC	Note 2, 4, 12, 16
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	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	Cardiac Adult								
	Cardiac Pediatric	P	P	P	P	P	P	BMDC	Note 2, 4, 6, 7,10, 12, 16
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel (Note 5)								
	Other (Specify)								

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

Note 1	For example: breast, testes, thyroid, prostate, etc.
Note 2	Dynamic TCE Technology
Note 3	Advanced SieClear
Note 4	eSieImage
Note 5	For example: abdominal, vascular (upper and lower)
Note 6	Stress Echo
Note 7	eSieMeasure
Note 8	eSieScan
Note 9	AHP
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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: L10-5v Transducer for use with:
ACUSON P500™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)	P	P	P		P	P	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.)	P	P	P		P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel (Note 5)	P	P	P		P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16
	Other (Specify)								

N = new indication; P = previously cleared K161787

Note 1	For example: breast, testes, thyroid, prostate, etc.
Note 2	Dynamic TCE Technology
Note 3	Advanced SieClear
Note 4	eSieImage
Note 5	For example: abdominal, vascular (upper and lower)
Note 6	Stress Echo
Note 7	eSieMeasure
Note 8	eSieScan
Note 9	AHP
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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: CW2 Transducer for use with:
ACUSON P500™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)								
	Neonatal Cephalic				P				
	Adult Cephalic				P				
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult				P				
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel (Note 5)				P				
	Other (Specify)								

N = new indication; P = previously cleared K141846

Note 1	For example: breast, testes, thyroid, prostate, etc.
Note 2	Dynamic TCE Technology
Note 3	Advanced SieClear
Note 4	eSieImage
Note 5	For example: abdominal, vascular (upper and lower)
Note 6	Stress Echo
Note 7	eSieMeasure
Note 8	eSieScan
Note 9	AHP
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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: CW5 Transducer for use with:
ACUSON P500™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)								
	Neonatal Cephalic				P				
	Adult Cephalic				P				
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult				P				
	Cardiac Pediatric				P				
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel (Note 5)				P				
	Other (Specify)								

N = new indication; P = previously cleared by K141846

Note 1	For example: breast, testes, thyroid, prostate, etc.
Note 2	Dynamic TCE Technology
Note 3	Advanced SieClear
Note 4	eSieImage
Note 5	For example: abdominal, vascular (upper and lower)
Note 6	Stress Echo
Note 7	eSieMeasure
Note 8	eSieScan
Note 9	AHP
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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: AcuNav 8F Transducer for use with:
ACUSON P500™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	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	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac	P	P	P	P	P	P	BMDC	Note 2, 4, 10, 12, 14, 16
	Other (Specify)								
Peripheral Vessel	Peripheral vessel (Note 5)								
	Other (Specify)								

N = new indication; P = previously cleared K141846

Note 1	For example: breast, testes, thyroid, prostate, etc.
Note 2	Dynamic TCE Technology
Note 3	Advanced SieClear
Note 4	eSieImage
Note 5	For example: abdominal, vascular (upper and lower)
Note 6	Stress Echo
Note 7	eSieMeasure
Note 8	eSieScan
Note 9	AHP
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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: AcuNav 10F Transducer for use with:
ACUSON P500™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	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	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac	P	P	P	P	P	P	BMDC	Note 2, 4, 10, 12, 14, 16
	Other (Specify)								
Peripheral Vessel	Peripheral vessel (Note 5)								
	Other (Specify)								

N = new indication; P = previously cleared K141846

Note 1	For example: breast, testes, thyroid, prostate, etc.
Note 2	Dynamic TCE Technology
Note 3	Advanced SieClear
Note 4	eSieImage
Note 5	For example: abdominal, vascular (upper and lower)
Note 6	Stress Echo
Note 7	eSieMeasure
Note 8	eSieScan
Note 9	AHP
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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: Soundstar 10F Transducer for use with:
ACUSON P500™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	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	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac	P	P	P	P	P	P	BMDC	Note 2, 4, 10, 12, 14, 15, 16
	Other (Specify)								
Peripheral Vessel	Peripheral vessel (Note 5)								
	Other (Specify)								

N = new indication; P = previously cleared K141846

Note 1	For example: breast, testes, thyroid, prostate, etc.
Note 2	Dynamic TCE Technology
Note 3	Advanced SieClear
Note 4	eSieImage
Note 5	For example: abdominal, vascular (upper and lower)
Note 6	Stress Echo
Note 7	eSieMeasure
Note 8	eSieScan
Note 9	AHP
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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: Soundstar eco 8F Transducer for use with:
ACUSON P500™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	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	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac	P	P	P	P	P	P	BMDC	Note 2, 4, 10, 12, 14, 15, 16
	Other (Specify)								
Peripheral Vessel	Peripheral vessel (Note 5)								
	Other (Specify)								

N = new indication; P = previously cleared K141846

Note 1	For example: breast, testes, thyroid, prostate, etc.
Note 2	Dynamic TCE Technology
Note 3	Advanced SieClear
Note 4	eSieImage
Note 5	For example: abdominal, vascular (upper and lower)
Note 6	Stress Echo
Note 7	eSieMeasure
Note 8	eSieScan
Note 9	AHP
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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: Soundstar eco 10F Transducer for use with:
ACUSON P500™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	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	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac	P	P	P	P	P	P	BMDC	Note 2, 4, 10, 12, 14, 15, 16
	Other (Specify)								
Peripheral Vessel	Peripheral vessel (Note 5)								
	Other (Specify)								

N = new indication; P = previously cleared K141846

Note 1	For example: breast, testes, thyroid, prostate, etc.
Note 2	Dynamic TCE Technology
Note 3	Advanced SieClear
Note 4	eSieImage
Note 5	For example: abdominal, vascular (upper and lower)
Note 6	Stress Echo
Note 7	eSieMeasure
Note 8	eSieScan
Note 9	AHP
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

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

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

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)*

☒ 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **ACUSON NX3 Elite™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)	P	P	P		P	P	P	
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic	P	P	P		P	P	P	
	Adult Cephalic	P	P	P	P	P	P	P	
	Trans-rectal	P	P	P		P	P	P	
	Trans-vaginal	P	P	P		P	P	P	
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	P	P	P		P	P	P	
	Musculo-skel. (Superfic)	P	P	P		P	P	P	
	Intra -vascular								
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	P	
	Cardiac Pediatric	P	P	P	P	P	P	P	
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)	P	P	P	P	P	P	P	
	Intra-Cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P	
	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

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

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

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

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **ACUSON NX3™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic	P	P	P		P	P	P	
	Adult Cephalic	P	P	P		P	P	P	
	Trans-rectal	P	P	P		P	P	P	
	Trans-vaginal	P	P	P		P	P	P	
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	P	P	P		P	P	P	
	Musculo-skel. (Superfic)	P	P	P		P	P	P	
	Intra -vascular								
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P		P	P	P	
	Cardiac Pediatric	P	P	P		P	P	P	
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-Cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P	
	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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **CH5-2** Transducer for use with:
ACUSON NX3 Elite™ Diagnostic Ultrasound System / ACUSON NX3™ 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 (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	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	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P	
	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

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

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

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

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **VF10-5** Linear Array Transducer for use with:
ACUSON NX3 Elite™ Diagnostic Ultrasound System / ACUSON NX3™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic								
	Adult Cephalic	P	P	P		P	P	P	
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	P	P	P		P	P	P	
	Musculo-skel. (Superfic)	P	P	P		P	P	P	
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P	
	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

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

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

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

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **VF12-4** Linear Array Transducer for use with:
ACUSON NX3 Elite™ Diagnostic Ultrasound System / ACUSON NX3™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic **– NX3 Elite only**	P	P	P		P	P	P	
	Adult Cephalic	P	P	P		P	P	P	
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	P	P	P		P	P	P	
	Musculo-skel. (Superfic)	P	P	P		P	P	P	
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P	
	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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **EC10-5w** Convex Array Transducer for use with:
ACUSON NX3 Elite™ 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 (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	
	Abdominal								
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic	P	P	P		P	P	P	
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	P	
	Trans-vaginal	P	P	P		P	P	P	
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-Cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral 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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **EC9-4** Convex Array Transducer for use with:
ACUSON NX3 Elite™ Diagnostic Ultrasound System / ACUSON NX3™ 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 (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	
	Abdominal								
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic – **NX3 Elite Only**	P	P	P		P	P	P	
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	P	
	Trans-vaginal	P	P	P		P	P	P	
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-Cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral 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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **CW2** Continuous Wave Doppler Transducer for use with: **ACUSON NX3 Elite™ 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 (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	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	Cardiac Adult				P				
	Cardiac Pediatric				P				
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral 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

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

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

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

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **CW5** Continuous Wave Doppler Transducer for use with: **ACUSON NX3 Elite™ 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 (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic				P				
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult				P				
	Cardiac Pediatric				P				
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral 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

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

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

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

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **P4-2** Phased Sector Array Transducer for use with:
ACUSON NX3 Elite™ Diagnostic Ultrasound System / ACUSON NX3™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic **– NX3 Elite Only**	P	P	P		P	P	P	
	Adult Cephalic	P	P	P		P	P	P	
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	P	
	Cardiac Pediatric	P	P	P	P	P	P	P	
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral 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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **VF16-5** Transducer for use with:
ACUSON NX3 Elite™ 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 (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic								
	Adult Cephalic	P	P	P		P	P	P	
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	P	P	P		P	P	P	
	Musculo-skel. (Superfic)	P	P	P		P	P	P	
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral 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

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

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

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **VF13-5sp** Transducer for use with:
ACUSON NX3 Elite™ 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 (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 2)	P	P	P		P	P	P	
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic								
	Adult Cephalic	P	P	P		P	P	P	
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	P	P	P		P	P	P	
	Musculo-skel. (Superfic)	P	P	P		P	P	P	
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel (Note 1)	P	P	P		P	P		
	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
Note 3 Combined modes are B/M, B/C, B/PWD, B/Power, B/C/PWD or CWD, B/C/M

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

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

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

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **C8F3** Transducer for use with:
ACUSON NX3 Elite™ Diagnostic Ultrasound System / ACUSON NX3™ 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 (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	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	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral 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

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

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

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

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **C8-5** Transducer for use with:
ACUSON NX3 Elite™ 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 (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	SmallOrgan (Note 1)								
	Neonatal Cephalic	P	P	P		P	P	P	
	Adult Cephalic	P	P	P		P	P	P	
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P		P	P	P	
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral 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

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

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

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

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **P8-4** Transducer for use with:
ACUSON NX3 Elite™ 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 (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	SmallOrgan (Note 1)								
	Neonatal Cephalic	P	P	P		P	P	P	
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P		P	P	P	
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral 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

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

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

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

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **11L4** Transducer for use with:
ACUSON NX3 Elite™ Diagnostic Ultrasound System /
ACUSON NX3™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic								
	Adult Cephalic	P	P	P		P	P	P	
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	P	P	P		P	P	P	
	Musculo-skel. (Superfic)	P	P	P		P	P	P	
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P	
	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

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

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

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

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **10MC3** Transducer for use with:
ACUSON NX3 Elite™ Diagnostic Ultrasound System /
ACUSON NX3™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	
	Abdominal								
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)	P	P	P		P	P	P	
	Neonatal Cephalic	P	P	P		P	P	P	
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	P	
	Trans-vaginal	P	P	P		P	P	P	
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral 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

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

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

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

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **BP10-3** Transducer for use with:
ACUSON NX3 Elite™ Diagnostic Ultrasound System /
ACUSON NX3™ 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)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	SmallOrgan (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	P	
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral 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

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

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

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

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **V5Ms** Transducer for use with:
ACUSON NX3 Elite™ 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 (Tracks1I& 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Note 3)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 2)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	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	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)	P	P	P	P	P	P	P	
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral 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

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

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

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

510(k)_____

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 – **Date Updated**: Oct. 13, 2020

Part 1. Sponsor:
Siemens Medical Solutions USA, Inc.,
Ultrasound Division
22010 South East 51St 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:	Diagnostic ultrasound system and transducers
Classification Name:	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	Radiology and Cardiology
CFR Section	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 51St 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 24th, 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 ACUSON Juniper	K201130 / May 26, 2020	IYN, IYO, ITX, OIJ
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

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.

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:

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, 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), trans-esophageal, 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).

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

Table 2: Comparison of Technological Characteristics with the Predicate Device

ACUSON Sequoia

Standard Feature	ACUSON Sequoia Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON Sequoia Diagnostic Ultrasound System K201462 (Predicate Device)	Comparison
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

Standard Feature	ACUSON Sequoia Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON Sequoia Diagnostic Ultrasound System K201462 (Predicate Device)	Comparison
	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.	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.	
Reusable?	Yes	Yes	Identical
Duration of Use	Limited (≤ 24 hours)	Limited (≤ 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	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	Identical

Standard Feature	ACUSON Sequoia Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON Sequoia Diagnostic Ultrasound System K201462 (Predicate Device)	Comparison
	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 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.	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 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 Curved Array Mechanical 3D Transducer	Curved Array Transducer Linear Array Transducer Phased Array Transducer Continuous Wave Transducers Curved Array Mechanical 3D Transducer	Identical
Acoustic Outputs Within Range?	Yes	Yes	Identical
Previously cleared Imaging Modes?	Yes	Yes	Identical

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

Standard Feature	ACUSON SC2000 Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON SC2000 Diagnostic Ultrasound System K200585 (Predicate Device)	Comparison
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	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	Identical

Standard Feature	ACUSON SC2000 Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON SC2000 Diagnostic Ultrasound System K200585 (Predicate Device)	Comparison
	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 heart, 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	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 heart, 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	

Standard Feature	ACUSON SC2000 Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON SC2000 Diagnostic Ultrasound System K200585 (Predicate Device)	Comparison
	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.	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.	

Standard Feature	ACUSON SC2000 Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON SC2000 Diagnostic Ultrasound System K200585 (Predicate Device)	Comparison
	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	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	

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 (≤ 24 hours)	Limited (≤ 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	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

Standard Feature	ACUSON SC2000 Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON SC2000 Diagnostic Ultrasound System K200585 (Predicate Device)	Comparison
	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 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.	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 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 Transesophageal Transducer Ultrasound Catheter	Curved Array Transducer Linear Array Transducer Phased Array Transducer Continuous Wave Transducers Transesophageal Transducer Ultrasound Catheter	Identical
Acoustic Outputs Within Range?	Yes	Yes	Identical

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

Standard Feature	ACUSON Freestyle Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON Freestyle Diagnostic Ultrasound System K200644 (Predicate Device)	Comparison
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).	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).	Identical
Reusable?	Yes	Yes	Identical
Duration of Use	Limited (≤ 24 hours)	Limited (≤ 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	Diagnostic ultrasound uses high-frequency (above the audible range) sound waves to produce an image of anatomical structures	Identical

Standard Feature	ACUSON Freestyle Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON Freestyle Diagnostic Ultrasound System K200644 (Predicate Device)	Comparison
	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 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.	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 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	Curved Array Transducer Linear Array Transducer	Curved Array Transducer Linear Array Transducer	Identical

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

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
Indications for Use	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	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	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
	{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	{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	

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 (≤ 24 hours)	Limited (≤ 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	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

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
	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 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.	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 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 Curved Array Mechanical 3D Transducer Transesophageal Transducer Ultrasound Catheter	Curved Array Transducer Linear Array Transducer Phased Array Transducer Continuous Wave Transducers Curved Array Mechanical 3D Transducer Transesophageal Transducer Ultrasound Catheter	Identical
Acoustic Outputs	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 Imaging Modes?	Yes	Yes	Identical
Biocompatibility	ISO 10993-1	ISO 10993-1	Identical

ACUSON P200

Standard Feature	ACUSON P200 Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON P200 Diagnostic Ultrasound System K191922 (Predicate Device)	Comparison
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	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	Identical

Standard Feature	ACUSON P200 Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON P200 Diagnostic Ultrasound System K191922 (Predicate Device)	Comparison
	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.	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.	
Reusable?	Yes	Yes	Identical
Duration of Use	Limited (≤ 24 hours)	Limited (≤ 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	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	Identical

Standard Feature	ACUSON P200 Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON P200 Diagnostic Ultrasound System K191922 (Predicate Device)	Comparison
	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 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.	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 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 Transesophageal Transducer	Curved Array Transducer Linear Array Transducer Phased Array Transducer Continuous Wave Transducers Transesophageal Transducer	Identical
Acoustic Outputs Within Range?	Yes	Yes	Identical

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

Standard Feature	ACUSON P500 Ultrasound System K# Pending (Subject Device)	ACUSON P500 Ultrasound System K163396 (Predicate Device)	Comparison
	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	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	

Standard Feature	ACUSON P500 Ultrasound System K# Pending (Subject Device)	ACUSON P500 Ultrasound System K163396 (Predicate Device)	Comparison
	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.	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 (≤ 24 hours)	Limited (≤ 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	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	Identical

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

Standard Feature	ACUSON NX3/NX3 Elite Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON NX3/NX3 Elite Diagnostic Ultrasound System K192835 (Predicate Device)	Comparison
	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. **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, Vascular (including	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. **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, 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. 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	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	

Standard Feature	ACUSON NX3/NX3 Elite Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON NX3/NX3 Elite Diagnostic Ultrasound System K192835 (Predicate Device)	Comparison
	Risk: A Consensus Statement from the American Society of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Medicine.".	Risk: A Consensus Statement from the American Society of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Medicine.".	
Reusable?	Yes	Yes	Identical
Duration of Use	Limited (≤ 24 hours)	Limited (≤ 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

Standard Feature	ACUSON NX3/NX3 Elite Diagnostic Ultrasound System K# Pending (Subject Device)	ACUSON NX3/NX3 Elite Diagnostic Ultrasound System K192835 (Predicate Device)	Comparison
	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.	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	**NX3** Curved Array Transducer Linear Array Transducer Phased Array Transducer Curved Array Mechanical 3D Transducer **NX3 Elite** Curved Array Transducer Linear Array Transducer Phased Array Transducer Continuous Wave Transducers Curved Array Mechanical 3D Transducer Transesophageal Transducer	**NX3** Curved Array Transducer Linear Array Transducer Phased Array Transducer Curved Array Mechanical 3D Transducer **NX3 Elite** Curved Array Transducer Linear Array Transducer Phased Array Transducer Continuous Wave Transducers Curved Array Mechanical 3D Transducer Transesophageal Transducer	Identical
Acoustic Outputs Within Range?	Yes	Yes	Identical
Previously cleared Imaging Modes?	Yes	Yes	Identical
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

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.