



May 31, 2018

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

Re: K181098

Trade/Device Name: ACUSON SC2000 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX, OBJ
Dated: May 24, 2018
Received: May 25, 2018

Dear Mr. Job:

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. 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.

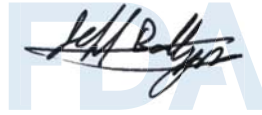
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, appearing to read "R. Ochs", is written over a large, light blue, semi-transparent "FDA" watermark.

for
Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K181098

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 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.

Catheters are 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 jugular 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)

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Diagnostic Ultrasound Indications for Use Form (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known): K181098

Device Name: **SC2000 Diagnostic Ultrasound System**

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

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: 3D	Other: Real Time 3D
Ophthalmic												
Fetal		P	P	P	P	P	P		P*	P		P
Abdominal		P	P	P	P	P	P		P*	P	P	
Intraoperative Abdominal		P	P	P	P	P	P		P*	P		
Intraoperative Neurological												
Pediatric		P	P	P	P	P	P		P*	P	P	P
Small Organ (specify)												
Neonatal Cephalic												
Adult Cephalic		P	P	P	P	P	P		P*	P		
Cardiac		P	P	P	P	P	P		P*	P	P	P
Trans-esophageal		P	P	P	P	P			P*		P	
Transrectal												
Transvaginal												
Transurethral												
Intra-Luminal		P	P	P	P	P	P		P*			P
Peripheral Vessel		P	P	P	P	P	P	P	P*	P		
Laparoscopic												
Musculo-skeletal Conventional		P	P	P		P	P	P	P*	P		
Musculo-skeletal Superficial		P	P	P		P	P	P	P*	P		
Other (Neonatal Cardiac)		P	P	P	P	P	P		P*	P		
Other (Intra-Cardiac)		P	P	P	P	P	P		P*			P
Other (Abdominal Vascular)		P	P	P	P	P	P		P*	P		

N=new indication. P = Previously Cleared in 510(k) K162221, K170315, K171766

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

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Diagnostic Ultrasound Indications for Use Form (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known): K181098

Device Name: **CW2**

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

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

N=new indication. Previously Cleared in 510(k) K162221, K170315, K171766

Additional Comments:

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known): K181098

Device Name: **4Z1c**

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

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal		P	P	P	P	P			P*	P	P
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P			P*	P	P
Small Organ (specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P			P*	P	P
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N=new indication. P = Previously Cleared in 510(k) K162221, K170315, K171766

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known): K181098

Device Name: **4V1c**

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

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

N=new indication. Previously Cleared in 510(k) K162221, K170315, K171766

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known): K181098

Device Name: **V5Ms**

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

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P			P*		P
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P			P*		P
Trans-esophageal		P	P	P	P	P			P*		P
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N=new indication. P = Previously Cleared in 510(k) K162221, K170315, K171766

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known): K181098

Device Name: **6C1HD**

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

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

N=new indication. P = Previously Cleared in 510(k) K162221, K170315, K171766

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known): K181098

Device Name: **Z6Ms**

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

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ (specify)											
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											
Intra-Luminal											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N=new indication. P = Previously Cleared in 510(k) K162221, K170315, K171766

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known): K181098

Device Name: V7M

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

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: 3D
Ophthalmic											
Fetal											
Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P			P*		P
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P			P*		P
Trans-esophageal		P	P	P	P	P			P*		P
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N=new indication. P = Previously Cleared in 510(k) K162221, K170315, K171766

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known): K181098

Device Name: **8V3**

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

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

N=new indication. Previously Cleared in 510(k) K162221, K170315, K171766

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known): K181098

Device Name: 9L4

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

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

N=new indication. P = Previously Cleared in 510(k) K162221, K170315, K171766

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known): K181098

Device Name: **10V4**

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

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

N=new indication. Previously Cleared in 510(k) K162221, K170315, K171766

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known): K181098

Device Name: **AcuNav 8F and 10F Ultrasound Catheter**

Intended Use: 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 as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P*		
Small Organ (specify) **											
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 in 510(k) K162221, K170315, K171766

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known): K181098

Device Name: **ACUSON AcuNav™ V 10F Ultrasound Catheter**

Intended Use: 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 as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P*		P
Small Organ (specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*		P
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal		P	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*		P

N=new indication. P = Previously Cleared in 510(k) K162221, K170315, K171766

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known): K181098

Device Name: **ACUSON AcuNav™ Volume 12F Ultrasound Catheter**

Intended Use: 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 as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P*		P
Small Organ (specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*		P
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal		P	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*		P

N=new indication. P = Previously Cleared in 510(k) K173618

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known): K181098

Device Name: **SoundStar™ 8F Ultrasound Catheter**

Intended Use: 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:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ (specify) **											
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 in 510(k) K140318**

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, **Biosense Webster Inc. 510(k) Clearance.

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known): K181098

Device Name: **SoundStar™ 10F Ultrasound Catheter**

Intended Use: 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:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ (specify) **											
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 in 510(k) K112050**, K162221, K170315, K171766

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, **Biosense Webster Inc. 510(k) Clearance.

(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 (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known): K181098

Device Name: **SoundStar™ *eco* 8F Ultrasound Catheter**

Intended Use: 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:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ (specify) **											
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 in 510(k) K163396, K140318**

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, **Biosense Webster Inc. 510(k) Clearance.

(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 (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known): K181098

Device Name: **SoundStar™ eco 10F Ultrasound Catheter**

Intended Use: 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:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ (specify) **											
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 in 510(k) K163396, K140318**

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, **Biosense Webster Inc. 510(k) Clearance.

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Concurrence of Center for Devices and Radiological Health (CDRH)

1.1.2 510(k) Summary

Date: March 12, 2018
Updated: May 23, 2018
Part 1. Sponsor: Siemens Medical Solutions USA, Inc.,
Ultrasound Division
685 East Middlefield Road
Mountain View, California 94043
Contact Person: Christine Dunbar
Tel: (925) 374-2045

Part 2. Device Name: ACUSON SC2000 Diagnostic Ultrasound System

Common Name: Diagnostic Ultrasound System with Accessories

Classification: Regulatory Class: II
Review Category: Tier II
Classification Panel: 90, Radiology

Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX
Diagnostic Intravascular Catheter	892.1200	90-OBJ

Manufacturing Site:

2500 Millbrook Drive, Suite B Buffalo Grove, Illinois USA

Legal Manufacturer: Siemens Medical Solutions USA, Inc.
685 East Middlefield Road
Mountain View, CA 94043

Part 3. Legally Marketed Predicate Devices

The ACUSON SC2000 Diagnostic Ultrasound System is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to the company's own products, the ACUSON SC2000, v5.0 under K171766, is the primary predicate device. Additionally, the currently cleared ACUSON AcuNav^{TM1} Volume Intracardiac Echocardiography (or ICE) Catheter (K173618) and support for the catheter updates to the currently cleared Biosense Webster SoundStarTM catheters (*eco* versions) are intended to be included in the transducers and catheter accessories provided with the ACUSON SC2000 Diagnostic Ultrasound System.

¹ ACUNAVTM is a trademark of Siemens Medical Solutions USA, Inc.

Part 4. Device Description

The ACUSON SC2000 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 and Harmonic Imaging on a Display. The transducer and catheter based transducers will follow Track 3 acoustic labeling (AIUM 1004, IEC 2007, AIUM/NEMA 2004a).

Additional features for the ACUSON SC2000 v5.1 update includes the Joystick remote control accessory that is intended to be used for interventional procedures with the ACUSON AcuNav Volume ICE catheter where remote control of the cursor is desired. The joystick plugs into the system and allows selected control panel and cursor events to be triggered via joystick movement and button-press.

During intracardiac imaging with ultrasound catheters, the ultrasound system is not within the sterile environment. You can use the joystick remote control within the sterile environment as an alternative to using the control panel on the ultrasound system. The joystick does not control the ultrasound catheter.

Part 5. Intended Use and Indications for Use Statements

5.1 SC2000 Diagnostic Ultrasound System, VB21A (v5.1)

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 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. Catheters are 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 jugular 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.

5.2 Intended Use - ACUSON AcuNav Volume Intracardiac Echocardiography Catheter (K173618) as cleared and is as follows:

The catheter is intended for intracardiac 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 catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

5.3 Intended Use – Biosense Webster Inc. SoundStar eco Diagnostic Ultrasound Catheter 8F & 10F, (Part Number M-5723-17 / Catalogue Number 10439011, compatible with Siemens Ultrasound Systems (K140318) as cleared and is as follows:

The Biosense Webster SOUNDSTAR® eco Diagnostic Ultrasound Catheter and related accessory devices are indicated 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. When used with compatible CARTO®D 3 EP Navigation Systems, the SOUNDSTAR® eco Catheter provides location information.

Part 6. Summary of Technological Characteristics

6.1 The ACUSON SC2000 VB21A (v5.1) Diagnostic Ultrasound System is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to the company's own products, the ACUSON SC2000 VB20A (v5.0) (K171766) and the ACUSON AcuNav™ Volume ICE Catheter (K173618) with regard to both intended use and technological characteristics. Both the subject ultrasound system and the predicate ultrasound

system function in the same manner as all diagnostic ultrasound systems and transducers including cardiac catheters.

The foundation of the ACUSON SC2000 VB21A (5.1) is the SC2000 VB20A (5.0) release with features and transducers integrated with the ACUSON SC2000 hardware and the updated v5.1 software developed for SC2000 platform. The updated SC2000 system VB21A includes the same currently cleared transducers and catheters in addition to the currently cleared ACUSON AcuNav Volume ICE Catheter and also supporting the SoundStar™ *eco* 8F and *eco* 10F Diagnostic Ultrasound Catheters which are developed, manufactured and distributed by Biosense Webster, Inc. under multiple clearances. In addition, the v5.1 update includes a new optional Joystick remote control accessory that plugs into the system and allows selected control panel and cursor events to be triggered via joystick movement and button-press. The joystick is extension of the keyboard. It works everywhere where these functions are available and with all transducers.

It is Siemens' opinion that the ACUSON SC2000 VB21A (v5.1) is substantially equivalent to the predicate devices with regard to both intended use, indications for use and technological characteristics.

6.2 - List of Technological Characteristics and SE Comparison Table

Feature / Characteristic	ACUSON SC2000 v5.1 Including Transducers This Submission	ACUSON SC2000 5.0 K171766 Including Transducers & AcuNav V ICE Catheter & 3 rd Party Catheters.	ACUSON AcuNav Volume ICE Catheter K173618
Indications for Use:			
- Fetal - Abdominal - Pediatric - Small Organ - Cardiac - Peripheral vessel - Musculo-skeletal (conventional) - Musculo-skeletal (superficial)	√ √ √ √ √ √ √ √	√ √ √ √ √ √ √ √	-- -- -- -- √ -- -- --
Frequencies Supported:	√ (1.7MHz~10MHz)	√ (1.7MHz~10MHz)	√ (4.0MHz~10MHz)
Modes:			
- B - M - PWD (Pulsed Wave Doppler) - CWD (Continuous Wave Doppler)	√ √ √ √	√ √ √ √	√ - √ √

Page 5 of 8

Feature / Characteristic	ACUSON SC2000 v5.1 Including Transducers This Submission	ACUSON SC2000 5.0 K171766 Including Transducers & AcuNav V ICE Catheter & 3 rd Party Catheters.	ACUSON AcuNav Volume ICE Catheter K173618
- eSie Left Heart Measurement Package - Volume Right Ventricular Analysis (RVA) - Stress Echo Package - Rapid Stress Volume Stress Echo App. - Cardiac Measurements and Calculations - syngo ® TrueFusion - Contrast Agent Imaging - Zoom & Pan - eSieScan (Protocols) - InFocus Coherent Technology - DICOM - DICOM SR	Added Manual Trace √ √ √ √ √ √ √ √ √ √	√ √ √ √ √ √ √ -- √ √	-- -- -- -- -- -- -- -- -- --
Wireless	√	√	--
Table Side Remote Control Joy Stick	New	--	--
Circle Tool	New	--	--
Motherboard Upgrade	New MBM250	√ MBM201+	--
Mechanical column upgrade	Lighter	--	--
Aluminum Card Cage	Weight reduction by 25 lbs	--	--
Monitor: 21" FPD	√	√	--
Output Display Standard (Track 3)	√	√	--
Patient Contact Materials	Tested to ISO 10993-1	Tested to ISO 10993-1	Tested to ISO 10993-1
UL 60601-1 Certified	√	√	√
Indications for Use	√	√	√
AcuNav™ V ICE Catheter	Supported	√	Currently cleared K170992
AcuNav™ Volume ICE Catheter (aka P6)	√	No	Currently cleared, K173618 on 12/19/2017.

Feature / Characteristic	ACUSON SC2000 v5.1 Including Transducers This Submission	ACUSON SC2000 5.0 K171766 Including Transducers & AcuNav V ICE Catheter & 3 rd Party Catheters.	ACUSON AcuNav Volume ICE Catheter K173618
Supports Third party US Catheters with Swift-Link connector:	√	√	N/A
SoundStar™ eco 8 French catheter ²	√	No	N/A
SoundStar™ eco 10 French catheter	√	No	N/A
SoundStar™ 8 French catheter ³	√	√	N/A
SoundStar™ 10 French catheter	√	√	N/A
SwiftLink Connector	√	√	√
CARTOSOUND ⁴ SW Module & CARTO 3 System	√	√ SoundStar 2D ICE Only.	-

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

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety and have been found to conform to applicable medical device safety standards. The ACUSON SC2000 Ultrasound system complies with the following standards:

- AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R) 2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2: 2007(Third Edition), Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
- IEC 60601-2-37:2007+A1:2015, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasound medical diagnostic and monitoring equipment.
- IEC 60601-2-18:2009, Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment.

² SoundStar and SoundStar eco catheters are products of Biosense Webster, Inc. (A Johnson & Johnson company) holds the 510(k) clearances for these devices.

³ SoundStar and SoundStar eco catheters are products of Biosense Webster, Inc. (A Johnson & Johnson company) holds the 510(k) clearances for these devices.

⁴ CARTOSOUND Module and CARTO 3 System are products of Biosense Webster, Inc. (A Johnson & Johnson company) holds the 510(k) clearances for these devices.

- IEC 62304:2006 Medical Device Software – Software Life Cycle Processes
- AIUM/NEMA UD-3:2004, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment.
- AIUM/NEMA UD-2:2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.
- ISO 10993-1:2009, Biological evaluation of Medical Devices
- IEC 62366:2014, Medical Devices – Application of Usability
- IEC 62359:2010, Ultrasonics – Field characterization – Test Methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields.

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

Since the ACUSON SC2000 VB21A (v5.1) Diagnostic Ultrasound System with the AcuNav Volume ICE Catheter use the same technology and principles as the existing predicate devices SC2000, VB20A (v5.0) K171766, and AcuNav Volume ICE Catheter (K173618) respectively, clinical studies were not required to support substantial equivalence.

Part 9. Summary

Intended uses and other key features are consistent with traditional clinical practice and FDA guidelines. The design and development process of the manufacturer conforms to 21 CFR 820 Quality System Regulation and ISO 13485:2003 quality system standards. The product is designed to conform to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. The SC2000 Diagnostic ultrasound systems have accumulated a long history of safe and effective performance.

Therefore, it is the opinion of Siemens Medical Solutions USA, Inc. that the ACUSON SC2000 VB21A (v5.1) system including the ACUSON AcuNav Volume ICE Catheter accessory, is substantially equivalent with respect to safety and effectiveness to the currently cleared predicate devices for the U.S. market.