DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

SIEMENS MEDICAL SOLUTIONS INC. ULTRASOUND GROUP
% Mr. MARK JOB
RESPONSIBLE THIRD PARTY OFFICIAL
1394 25TH STREET, NW
BUFFALO MN 55313

September 6, 2016

Re: K162221
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: August 4, 2016
Received: August 8, 2016

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162221

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, M-Mode (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 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

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

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.

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"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 (Per Appendix G, FDA Ultrasound Guidance)

510(k) Number (if known):

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) K142628

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)

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

510(k) Number (if known):

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) K142628

Additional Comments:

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

510(k) Number (if known):

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) K142628

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):

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) K142628

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):

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) K142628

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):

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) K142628

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):

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) K142628

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):

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) K142628

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):

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) K142628

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):

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) K142628

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):

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) K142628

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):

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) K142628

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):

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) K142628

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):

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) K142628

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)

510(k) Summary

Sponsor: Siemens Medical Solutions, Inc.
Ultrasound Division
685 East Middlefield Road
Mountain View, California 94043

Contact Person: Kevin Kong
Title: Regulatory Affairs Specialist
Telephone: (650) 969-9112

Submission Date: July 20, 2016

Device Name: ACUSON SC2000™ Diagnostic Ultrasound System

Common Name: Diagnostic Ultrasound System

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

Ultrasonic Pulsed Doppler Imaging System

- 21 CFR # 892.1550
- Product Code IYN

Ultrasonic Pulsed Echo Imaging System

- 21 CFR # 892.1560
- Product Code IYO

Diagnostic Ultrasound Transducer

- 21 CFR # 892.1570
- Product Code ITX

Diagnostic Intravascular Catheter

- 21 CFR # 870.1200
- Product Code OBJ

Legally Marketed Predicate Devices

The ACUSON SC2000™ Ultrasound System in this 510(k) is a modification to the previously cleared ACUSON SC2000™ Ultrasound System (K142628) and substantially equivalent.

Device Description:

The ACUSON SC2000™ Diagnostic Ultrasound System is a multi-purpose mobile, software controlled diagnostic ultrasound system, with an on-screen display for thermal and mechanical indices, related to potential bio-effect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data, and display it in the following modes (The following modes below can be operated in combination or individually):

- B-Mode
- M-Mode
- Pulsed (PWD) Doppler Mode
- Continuous (CWD) Doppler Mode
- Color Doppler Mode
- Amplitude Doppler Mode
- Color Velocity Imaging
- 3D Imaging,
- 4D Imaging (3D imaging in real time)

Intended Use

The ACUSON SC2000™ Diagnostic Ultrasound 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, M-Mode (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 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 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.

Substantial Equivalence

The submission device is a modification to ACUSON SC2000™ Diagnostic Ultrasound System as previously cleared in K142628. With regard to both intended use and technological characteristics, the modified device is substantially equivalent to the previously cleared device (K142628).

System Substantial Equivalence Table

Description	Acuson SC2000™ K142628	Acuson SC2000™ This submission
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, M-Mode (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 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	Same

Description	Acuson SC2000™ K142628	Acuson SC2000™ This submission
	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.	

Description	Acuson SC2000™ K142628	Acuson SC2000™ This submission
Product Code(s)	System: IYO, IYN Transducers: ITX Intravascular Catheter: OBJ	Same
Transducer Types	-Matrix Array -Phased Array -Linear Array -Curved Array	Same
Modes of Operation	-B Mode -M Mode -Pulse Wave Doppler Mode (PWD Mode) -Continuos Doppler Mode (CWD) -Color Doppler Mode -Amplitude Doppler Mode -Color Velocity Imaging -3D Imaging -4D Imaging	Same

Description	Acuson SC2000™ K142628	Acuson SC2000™ This submission
Imaging		
Multi-Hertz multiple frequency imaging	X	Same
Output display standard compliance	X	Same
Dual screen	X	Same
Acoustic clip capture	X	Same
Cardiac Measurements and Calculations	X	Same
DTI™ Doppler tissue imaging	X	Same
Contrast Imaging		
Contrast pulse sequencing technology (CPS)	X	Same
TEQ and NTEQ ultrasound technology for CPS	X	Same
Vascular Imaging		
Vascular Calculation and Measurements	X	Same
Spatial Compounding	X	Same
Semi Auto Doppler Option (Trace Assist)	X	Same
Transcranial Imaging	X	Same
Connectivity		
Wireless Network Connectivity	X	Same
DICOM Compatibility	X	Same

A brief discussion of the non-clinical test submitted, referenced, or relied on in the special 510(k) for determination of substantial equivalence.

The devices have 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 with the applicable medical device safety standards. The systems comply with the following standards:

- AAMI/ANSI 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility
- IEC 60601-2-37 Medical Electrical Equipment – Part 2-37: Particular Requirements For the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and monitoring Equipment
- IEC 62366 Medical Devices – Application of Usability
- IEC 62304 Medical Device Software – Software Life Cycle Processes
- IEC 60601-2-18 Medical Electrical Equipment – Part 2-18 Particular Requirements For Basic and Essential Performance of Endoscopic Equipment
- NEMA UD-3 Standard Real-Time Display of Thermal and Mechanical Acoustic Output indices on Diagnostic Ultrasound Equipment
- NEMA UD-2 Acoustic Output Measurement Standard for Diagnostic Ultrasound
- ISO 10993-1 Biological Evaluation of Medical Devices

Summary discussion of the clinical tests submitted, referenced, or relied on for determination of substantial equivalence

The ACUSON SC2000™ Diagnostic Ultrasound System is a class II device using the same technology and operating principle as the predicate devices, no clinical data is required.

Conclusion

As shown by the substantial equivalence table above, the modified ACUSON SC2000™ Diagnostic Ultrasound System is substantially equivalent as the predicate ACUSON SC2000™ Diagnostic Ultrasound System (K142628).