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

January 12, 2017

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

Re: K163635
Trade/Device Name: ACUSON S1000, S2000, S3000™ Diagnostic Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX, OBJ
Dated: December 21, 2016
Received: December 22, 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,

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

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)*
K163635

Device Name
Acuson S1000, S2000, S3000™ Diagnostic Ultrasound Systems

Indications for Use *(Describe)*
The ultrasound imaging systems are intended for the following applications: Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Transcranial, OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures), Cardiac, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

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

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

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

Transducer Indications for Use are on the attached pages.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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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

510 (k) Number (if known): _____

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

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

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

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

Additional Comments:

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

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____

Device Name: **12L4 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**

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

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

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

Additional Comments:

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____

Device Name: **CW2 Probe for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**

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

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

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

Additional Comments:

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

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____

Device Name: **CW5 Probe for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**

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

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

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

Additional Comments:

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____

Device Name: **EC9-4 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**

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

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

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

Additional Comments:

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____

Device Name: **MC9-4 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**

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

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

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

Additional Comments:

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____

Device Name: **9L4 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**

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

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

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

Additional Comments:

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____

Device Name: **14L5 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**

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

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

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

Additional Comments:

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____
Device Name: **4P1 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Additional Comments:

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

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Concurrence of Center for Devices and Radiological Health(CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____

Device Name: **6C2 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**

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

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

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

Additional Comments:

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

Note 2 For example: vascular, abdominal

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____

Device Name: **4C1 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**

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

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

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

Additional Comments:

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

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

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____
Device Name: **6C1 HD Transducer for use with ACUSON S2000 and S3000 Ultrasound Systems**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Additional Comments:

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

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____

Device Name: **8C3 HD Transducer for use with ACUSON S2000 and S3000 Ultrasound Systems**

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

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

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

Additional Comments:

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

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____

Device Name: **4V1 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**

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

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

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

Additional Comments:

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

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____
Device Name: **10V4 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Additional Comments:

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

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____

Device Name: **14L5 SP Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**

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

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

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

Additional Comments:

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____

Device Name: **7CF2 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**

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

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

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

Additional Comments:

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____

Device Name: **7CF1 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**

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

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

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

Additional Comments:

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____

Device Name: **9EVF4 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**

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

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

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

Additional Comments:

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

Note 2 For example: vascular, abdominal

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____
Device Name: **V5Ms Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Additional Comments:

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____
Device Name: **18L6 HD Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Additional Comments:

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

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____
Device Name: **8V3 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____

Device Name: **4V1c Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**

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

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

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

Additional Comments:

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

Note 2 For example: vascular, abdominal

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____
Device Name: **EV-8C4 Transducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

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

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

Additional Comments:

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____

Device Name: **V7MTransducer for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**

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

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

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

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____

Device Name: **AcuNav 8F Ultrasound Catheter for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**

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

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

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

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler

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Concurrence of Center for Devices and Radiological Health (CDRH)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____

Device Name: **AcuNav 10F Ultrasound Catheter for use with ACUSON S1000, S2000 and S3000 Ultrasound Systems**

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

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

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

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Colo Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler

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Concurrence of Center for Devices and Radiological Health (CDRH)

510(k) Summary

July 23, 2016

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

Contact Person: Sulgue Choi
Telephone: (425) 281-9898

2. Device Name: Acuson S1000, S2000, S3000™ Diagnostic Ultrasound Systems

May also be marketed as:
ACUSON Oxana 1 Ultrasound System
ACUSON Oxana 2 Ultrasound System
ACUSON Oxana 3 Ultrasound System
ACUSON Oxana 2 Ultrasound Automated Breast Volume Scanner
(ACUSON Oxana 2 ABVS)
ACUSON Ultrasound Automated Breast Volume Scanner
(ACUSON ABVS)

Common Name: Diagnostic Ultrasound System

Classification:

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

Ultrasonic Pulsed Doppler Imaging System Product Code 90-IYN	FR # 892.1550
Ultrasonic Pulsed Echo Imaging System Product Code 90-IYO	FR # 892.1560
Diagnostic Ultrasound Transducer Product Code 90-ITX	FR # 892.1570
Diagnostic Ultrasound Catheter Product Code OBJ	FR # 870.1200

Manufacturing Site:

Siemens Medical Solutions USA, Inc.,
2500 Millbrook Drive, Suite B
Mountain View, California 94043
Buffalo Grove, IL 60089

3. Legally Marketed Predicate Devices

The modified Acuson S1000, S2000, S3000 Ultrasound Systems are substantially equivalent to the company's own systems:

System	510(k)
S1000	K162243
S2000	K162243
S3000	K162243

4. Device Description:
The ultrasound systems are multi-purpose mobile, software controlled diagnostic ultrasound systems with and on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms. The function is to acquire primary or secondary harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Amplitude, Doppler Mode, a combination of modes, or Harmonic Imaging and 3D/4D Imaging on a Flat Panel Display.

5. Intended Use

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

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

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

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

6. Summary of Technological Characteristics

The modified Acuson S1000, S2000, S3000 Ultrasound Systems are the same as the company’s own previously cleared Acuson S1000, S2000, S3000 Ultrasound Systems (K162243) with regard to both intended use and technological characteristics. Both the subject ultrasound systems and the predicate ultrasound systems function in the same manner as all diagnostic ultrasound systems and transducers.

Feature / Characteristic	Acuson S1000/S2000/S3000 This Submission	Acuson S1000/S2000/S3000 K# 162243
Indications for Use:		
▪ Fetal	√	√
▪ Abdominal	√	√
▪ Intraoperative	√	√
▪ Intraoperative neurological	--	--
▪ Pediatric	√	√
▪ Small Organ	√	√
▪ Neonatal cephalic	√	√
▪ Adult Cephalic	√	√
▪ Cardiac	√	√
▪ Trans-esophageal	√	√
▪ Transrectal	√	√
▪ Transvaginal	√	√
▪ Peripheral vessel	√	√
▪ Laparoscopic	--	--
▪ Musculo-skeletal (conventional)	√	√
▪ Musculo-skeletal (superficial)	√	√
Center Frequencies Supported:		
▪ 2.0 MHz	√	√
▪ 3.0 MHz	√	√
▪ 3.2 MHz	√	√
▪ 3.3 MHz	√	√
▪ 4.2 MHz	√	√
▪ 4.4 MHz	√	√
▪ 4.8 MHz	√	√
▪ 5.0 MHz	√	√
▪ 5.2 MHz	√	√
▪ 6.0 MHz	√	√
▪ 6.5 MHz	√	√
▪ 6.9 MHz	√	√
▪ 9.5 MHz	√	√
▪ 10.0 MHz	√	√
Modes:		
▪ B	√	√
▪ Parallel processing in B mode	√	√
▪ M	√	√
▪ PWD (Pulsed Wave Doppler)	√	√
▪ CWD (Continuous Wave Doppler)	√	√
▪ D (Color Doppler)	√	√
▪ Amplitude Doppler	√	√
▪ Combined (BMDC)	√	√
Features:		
Quad processing in color	√	√
▪ Native™ tissue harmonic imaging	√	√

Feature / Characteristic	Acuson S1000/S2000/S3000 This Submission	Acuson S1000/S2000/S3000 K# 162243
▪ SieScape™ panoramic imaging	√	√
▪ Color SieScape™ panoramic imaging	√	√
▪ 3-Scape™ real-time 3D imaging	√	√
▪ fourSight™ 4D transducer technology	√	√
▪ TEQ™ ultrasound technology	√	√
▪ Cardiac Imaging physiological signal display	√	√
▪ syngo ® Auto OB measurements	√	√
▪ Advanced SieClear™ spatial compounding	√	√
▪ STIC (Fetal Heart Imaging)	√	√
▪ Amnioscopic rendering	√	√
▪ Cadence contrast agent imaging	√	√
▪ Clarify™ vascular enhancement technology	√	√
▪ eSie™ Touch elasticity imaging	√	√
▪ syngo ® Auto Left heart	√	√
▪ syngo ® Velocity Vector Imaging	√	√
▪ Semi Auto-segmentation (eSie Calc)	√	√
▪ Custom Tissue Imaging / Speed of Sound	√	√
▪ AHP	√	√
▪ eSie Fusion (S3000 only)	√	√
▪ VTI (S2000 & S3000 only)	√	√
Wireless	√	√
Monitor: 21” FPD	√	√
Output Display Standard (Track 3)	√	√
Patient Contact Materials	Tested to ISO 10993-1	Tested to ISO 10993-1
UL 60601-1 Certified	√	√
Indications for Use	√	√

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 has been found to conform with applicable medical device safety standards. The system complies with the following voluntary standards:

- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- IEC 62359, Test methods for the determination of thermal and mechanical indices
- Safety and EMC Requirements for Medical Equipment
  - IEC 60601-1
  - IEC 60601-1-2
  - IEC 60601-2-18
  - IEC 60601-2-37
- ISO 10993-1 Biocompatibility

Cleared patient contact materials, electrical and mechanical safety are unchanged. Testing was performed to verify the software release.

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

Since the S1000, S2000, S3000 systems in this submission use the same technology and principles as existing devices, clinical studies were not required to support substantial equivalence.

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 with 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. Therefore it is the opinion of Siemens Medical that the S1000, S2000 and S3000 systems are substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.