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

August 16, 2017

SIEMENS HEALTHCARE
C/O Mr. MARK JOB
Responsible Third Party Official
1394 25TH STREET, NW
BUFFALO MN 55313

Re: K172162
Trade/Device Name: Acuson S3000 S2000 S1000 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: July 10, 2017
Received: July 18, 2017

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,

Michael D. O'Hara For

Robert Ochs
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172162

Device Name
ACUSON S3000™, S2000™, S1000™ Diagnostic Ultrasound System

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.

The 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.

1.3 Indications for Use Forms

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **ACUSON S3000, S2000, S1000 Diagnostic 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	Note 2,3,4,5,7,8,10, 11, 13
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,6, 7,8,10, 11, 13, 16,18,20
Intraoperative (Note 9)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14
Intraoperative Neurological		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,6, 7,8,10, 11
Small Organ (Note 1)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,6, 7,8,10, 11,14, 16,18,19,20
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Cardiac		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10,15
Trans-esophageal		P	P	P	P	P	P		BMDC	Note 4
Transrectal		P	P	P		P	P		BMDC	Note 2,3,4,5,6, 7,8,10, 11,14
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note2,3,4,5,7,8,10, 11,14,15
Laparoscopic										
Musculo-skeletal Conventional		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14,
Musculo-skeletal Superficial		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14,
Other (specify) Neonatal cardiac		P	P	P	P	P	P		BMDC	Note 3,4,10,17

N = new indication; P = previously cleared by K162243; K130739 (VTI); K131164(VTQ); K130881 (VTIQ)

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 9 For example: vascular, abdominal
Note 10 Clarify VE technology
Note 11 Advanced Sieclear spatial compounding
Note 13 STIC
Note 14 eSie™ Touch elasticity imaging / FTI
Note 15 AHP
Note 16 Custom Tissue Imaging
Note 17 eSie Fusion
Note 18 VTI
Note 19 VTIQ
Note 20 VTQ

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

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **CW2 Probe**
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 (Note 9)					P					
Intraoperative Neurological										
Pediatric					P					
Small Organ (Note 1)					P					
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 9 For example: vascular, abdominal

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

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510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **CW5 Probe**
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 (Note 9)					P					
Intraoperative Neurological					P					
Pediatric					P					
Small Organ (Note 1)					P					
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 9 For example: vascular, abdominal

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

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510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **EC9-4 Curved Array Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,6,7,8,10, 11, 17
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal		P	P	P		P	P		BMDC	Note 2,3,4,5, 6, 7,8,10, 11,14
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
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 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie™ Touch elasticity imaging / FTI
Note 17 eSie™ Fusion

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

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **9L4 Linear Array Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Abdominal		P	P	P		P	P		BMDC	Note 6,18,20 – any others?
Intraoperative										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,6, 7,8,10, 11
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,6,7,8,10, 11,14, 16,18,19,20
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Adult Cephalic		P	P	P		P	P			
Cardiac		P	P	P		P	P		BMDC	Note 15
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5, 7,8,10, 11, 14,15
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14
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 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear
Note 14 eSie™ Touch elasticity imaging / FTI
Note 15 AHP
Note 16 Custom Tissue Imaging
Note 18 VTI
Note 19 VTIQ
Note 20 VTQ

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

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **14L5BV Multi-D Array Transducer for use on S2000**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14, 16
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 K081148

Additional Comments:
Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie™ Touch elasticity imaging / FTI
Note 16 Custom Tissue Imaging

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

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **4P1 Phased Array Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Cardiac		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
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 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

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

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **6C2 Curved Array Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14, 16, 17
Intraoperative										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie™ Touch elasticity imaging / FTI
Note 16 Custom Tissue Imaging
Note 17 eSie Fusion

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

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **4C1 Curved Array Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10, 11,18,19,20
Abdominal		P	P	P	P	P	P		BMDC	Note2,3,4,5,6,7,8, 10, 11, 14, 16, 17
Intraoperative										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P			Note 6 – others?
Small Organ		P	P	P	P	P	P		BMDC	
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 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie™ Touch elasticity imaging / FTI
Note 16 Custom Tissue Imaging
Note 17 eSie Fusion
Note 18 VTI
Note 19 VTIQ
Note 20 VTQ

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

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **6C1HD Curved Array Transducer HD**
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	Note 2,3,4,5,7,8,10, 11
Abdominal		P	P	P	P	P	P		BMDC	Note2,3,4,5,6,7,8, 10,11,14,16,17,18,1 9,20
Intraoperative										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 6 – others?
Small Organ		P	P	P	P	P	P		BMDC	
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 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie™ Touch elasticity imaging / FTI
Note 16 Custom Tissue Imaging
Note 17 eSie Fusion
Note 18 VTI
Note 19 VTIQ
Note 20 VTQ

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

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **8C3HD Curved Array Transducer for use with ACUSON S3000**
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	Note 2,3,4,5,7,8,10, 11
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 14, 16
Intraoperative										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Small Organ		P	P	P		P	P		BMDC	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA K#121138, K162243

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie™ Touch elasticity imaging / FTI
Note 16 Custom Tissue Imaging

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

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510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 14,16,17,18,19,20
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 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie™ Touch elasticity imaging / FTI
Note 16 Custom Tissue Imaging
Note 17 eSie Fusion
Note 18 VTI
Note 19 VTIQ
Note 20 VTQ

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

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510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ										
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac		P	P	P	P	P	P		BMDC	Note 3,4
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

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510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **14L5 SP Linear Array Transducer**
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 (Note 9)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Neurological		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14, 16
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P		P	P		BMDC	Note 15
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note2,3,4,5,7,8,10, 11,14,15
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
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 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 9 For example: vascular, abdominal
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie™ Touch elasticity imaging / FTI
Note 15 AHP
Note 16 Custom Tissue Imaging

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

Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **7CF2 Curved array mechanical 3D transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,13
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11, 13
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 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 13 STIC

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510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **9EVF4 Curved Array Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8, 10,11, 13
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8, 10,11
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8, 10,11
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 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 13 STIC

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510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

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

Clinical Application	Mode of Operation									
	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	Note 4
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 4 Tissue Equalization Technology

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510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14, 16
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P		P	P		BMDC	Note 15
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14,15
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10, 11,14
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 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie™ Touch elasticity imaging / FTI
Note 15 AHP
Note 16 Custom Tissue Imaging

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510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **8V3 Phased Array Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ										
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac		P	P	P	P	P	P		BMDC	Note 3,4
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	Note 3,4

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

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

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510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **4V1c Phased Array Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10
Abdominal		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10
Intraoperative		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10
Intraoperative Neurological		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10
Pediatric		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10
Small Organ										
Neonatal Cephalic										
Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10
Cardiac		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10 15
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10 15
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify) Neonatal Cardiac		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10

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

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology
Note 15 AHP

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510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **EV8C4 Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10
Abdominal		P	P	P	P	P	P		BMDC	Note 2 3 4 5 6 7 8 10
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal		P	P	P	P	P	P		BMDC	Note 2 3 4 5 7 8 10
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 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

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510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name: **V7M TEE Transducer**
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) *	Harmonic Imaging	Other (Specify)
Ophthalmic											
Fetal											
Abdominal		P	P	P	P	P	P		P	P	Note 4
Intraoperative											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P	P	Note 4
Small Organ (specify)**											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P	P	Note 4
Trans-esophageal		P	P	P	P	P	P		P	P	Note 4
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

Note 2 Ensemble tissue harmonic imaging
Note 4 Tissue Equalization Technology
Note 10 Clarify VE vascular enhancement technology

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

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510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

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

Intended Use: ɔuCatheter 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**
Ophtalmic										
Fetal										
Abdominal										
Intraoperative										
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	

P=Previously cleared by the 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,

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

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510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

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

Intended Use: uCatheter 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**
Ophtalmic										
Fetal										
Abdominal										
Intraoperative										
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	

P=Previously cleared by the 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,

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510(k)_____

Diagnostic Ultrasound Indications for Use Form

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____
Device Name: **MC9-4 Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10,11
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10,11
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ (note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10,11,14
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10,11,14
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10,11
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 i.e.: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 Siescape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE Vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie Touch elasticity imaging/FTI

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

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Division Sign-Off - Office of In Vitro Diagnostic Devices

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): _____
Device Name: 14L5 Transducer
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ (note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10,11,14, 16
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,6,7,8,10,11,1 4
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10,11,14
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments:

Note 1 i.e.: breast, testes, thyroid, penis, prostate, etc.
Note 2 For example: vascular, abdominal
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 Siescape real-time 3D imaging
Note 6 Cadence contrast agent imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE Vascular enhancement technology
Note 11 Advanced Sieclear spatial compounding
Note 14 eSie Touch elasticity imaging/FTI
Note 16 Custom Tissue Imaging

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

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510(k)_____

510(k) Summary
Prepared April 24, 2017

1. Sponsor: Siemens Medical Solutions USA, Inc.,

Ultrasound Division
685 East Middlefield Road
Mountain View, California 94043

Contact Person: Shelly Pearce
Telephone: (650)279-0134

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

Common Name: Diagnostic Ultrasound System

Classification:

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

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

3. Legally Marketed Predicate Devices

The modified ACUSON S3000™, S2000™, S1000™ Ultrasound Systems is substantially equivalent to the company's own S3000 Ultrasound System (K163635) and Philips QLAB (K0132165).

4. Device Description:

The ACUSON S3000, S2000, S1000 Ultrasound Systems are a multi-purpose mobile, software controlled diagnostic ultrasound system with and 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 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. It is substantially equivalent to the S3000 system (K163635) and QLAB (K132165) which are legally marketed devices.

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 AcuNav 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.

6. Summary of Technological Characteristics – New Device Compared to Predicate

Feature / Characteristic	Acuson S3000, S2000, S1000	Acuson S3000,S2000 , S1000 K163635	QLAB K132165
Indications for Use:			
▪ Fetal	√	√	
▪ Abdominal	√	√	
▪ Intraoperative abdominal and vascular	√	√	
▪ Intraoperative neurological	--	--	
▪ Pediatric	√	√	
▪ Small Organ	√	√	
▪ Neonatal cephalic	√	√	
▪ Adult Cephalic	√	√	
▪ Cardiac	√	√	
▪ Trans-esophageal	√	√	
▪ Transrectal	√	√	
▪ Transvaginal	√	√	
▪ Peripheral vessel	√	√	

Feature / Characteristic	Acuson S3000, S2000, S1000	Acuson S3000,S2000 , S1000 K163635	QLAB K132165
■ 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	√	√	
■ 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	√	√	

Feature / Characteristic	Acuson S3000, S2000, S1000	Acuson S3000,S2000 , S1000 K163635	QLAB K132165
▪ Contrast Dynamics	√		√
▪ Clarify™ vascular enhancement technology	√	√	
▪ eSie™ Touch elasticity imaging	√	√	
▪ syngo ® Auto Left heart	Tested to ISO 10993-1	√	
▪ syngo ® Velocity Vector Imaging	√	√	
▪ Semi Auto-segmentation (eSie Calc)	√	√	
▪ Custom Tissue Imaging / Speed of Sound	√	√	
▪ VTI (S2000, S3000)	√	√	
▪ VTIQ (S2000, S3000)	√	√	
▪ VTQ (S2000, S3000)	√	√	
▪ AHP	√	√	
▪ Monitor: 19" FPD	√	√	
▪ eSie Fusion	√	√	
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
  - UL/IEC 60601-1
  - AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012
  - 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 ACUSON S3000, S2000, S1000 Ultrasound Systems use the same technology and principles as existing devices, clinical data is not required.

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 with applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore it is the opinion of Siemens Medical that the ACUSON S3000, S2000, S1000 is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.