Siemens Medical Solutions USA, Inc.
% Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

June 24, 2020

Re: K201462
Trade/Device Name: ACUSON Sequoia Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, OIJ
Dated: June 1, 2020
Received: June 2, 2020

Dear Prithul Bom:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

K201462

Device Name
ACUSON Sequoia Diagnostic Ultrasound System

Indications for Use *(Describe)*

The ACUSON Sequoia ultrasound imaging system is intended to provide images of, or signals from, inside the body by an appropriately trained healthcare professional in a clinical setting for the following applications: Fetal, Abdominal, Pediatric, Neonatal Cephalic, Small Parts, OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures), Cardiac, Pelvic, Vascular, Adult Cephalic, Musculoskeletal and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures for fetal, abdominal, pediatric, small organ, cardiac, transrectal, transvaginal, peripheral vessel, musculoskeletal and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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

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

N = new indication; P = previously cleared by K200707

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

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

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

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

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

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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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: **5C1 Curved Array Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

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

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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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: **9C3 Curved Array Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

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

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

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

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

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

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

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

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

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

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

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

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

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

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

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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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: **CW2 Continuous Wave Transducer**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

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

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

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

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

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

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

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

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

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

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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

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

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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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: **9VE4 Curved Endovaginal Mechanical 3D Transducer**

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

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

N = new indication; P = previously cleared by K200707

Additional Comments:

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

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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)_____

510(k) Summary

Date: May 18, 2020

1. Sponsor:

Siemens Medical Solutions USA, Inc.
Ultrasound Division
22010 South East 51st Street
Issaquah, Washington 98029

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

2. Device Name: ACUSON Sequoia Diagnostic Ultrasound System

Common Name: Diagnostic Ultrasound System with Accessories

Classification:

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

Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX
Biopsy Needle Guide Kit	892.1560	90-OIJ

Manufacturing Site: Siemens Medical Solutions USA, Inc.
22010 South East 51st Street,
Issaquah, Washington 98029, UNITED STATES

3. Legally Marketed Predicate Devices

The ACUSON Sequoia Diagnostic Ultrasound System is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to the company's own products, the ACUSON Sequoia (K200707) which is primary predicated device and the ACUSON S family (K172162).

4. Device Description

The ACUSON Sequoia Diagnostic Ultrasound System is a multi-purpose mobile, software controlled, diagnostic ultrasound system with an on-screen display of thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to transmit and receive

ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Color M Mode, Doppler Tissue Mode, Amplitude Doppler Mode, a combination of modes, Panoramic Imaging, Contrast agent Imaging, Virtual Touch Strain Imaging, Virtual Touch – pSWE Imaging, Virtual Touch – SWE Imaging, syngo Velocity Vector Imaging, Custom Tissue Imaging, 3D/4D Volume Imaging and Harmonic Imaging on a Display.

5. Intended Use/Indications for Use

The ACUSON Sequoia ultrasound imaging system is intended to provide images of, or signals from, inside the body by an appropriately trained healthcare professional in a clinical setting for the following applications: Fetal, Abdominal, Pediatric, Neonatal Cephalic, Small Parts, OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures), Cardiac, Pelvic, Vascular, Adult Cephalic, Musculoskeletal and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures for fetal, abdominal, pediatric, small organ, cardiac, transrectal, transvaginal, peripheral vessel, musculoskeletal and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

6. Summary of Technological Characteristics

The modified ACUSON Sequoia Ultrasound System is the same as the company's own previously cleared ACUSON Sequoia (K200707) and the ACUSON S family (K172162) with regard to both intended use and technological characteristics. Both the modified ultrasound system under this review and the predicate ultrasound systems function in the same manner as all diagnostic ultrasound systems and transducers.

The submission device differs from the predicated devices as following:

- The modified ACUSON Sequoia Ultrasound System includes the addition of the 9VE4 transducer which is substantially equivalent to the 9EVF4 transducer previously cleared on the ACUSON S family (K172162).
- The modified ACUSON Sequoia Ultrasound System includes the expansion of the 'Pediatric' clinical application for 18H6 transducer which was already cleared on the ACUSON Sequoia (K200707)
- Also this Traditional 510(k) includes 3D/4D Volume Imaging Mode which are cleared on the ACUSON S family (K172162) to enable an improved customer experience.

All other hardware and software features of the ACUSON Sequoia Diagnostic Ultrasound device remain unchanged. The foundation of the ACUSON Sequoia (this submission) is the ACUSON Sequoia(K200707) with features and transducers integrated with the ACUSON Sequoia(K200707) hardware and the ACUSON Sequoia (this submission) reuse software developed for Sequoia(K200707) mainly as well as 9VE4 transducer from S family (K172162).

The submission device is substantially equivalent to the predicate with regards to both intended use and technological characteristics.

Feature / Characteristic	ACUSON Sequoia This Submission	ACUSON Sequoia K# 200707 Predicate device	ACUSON S family S1000/S2000/S3000 K# 172162 Reference device
Indications for Use:			
▪ Fetal	√	√	
▪ Abdominal	√	√	
▪ Pediatric	√	√	
▪ Small Organ	√	√	
▪ Cardiac	√	√	
▪ Transrectal	√	√	
▪ Transvaginal	√	√	
▪ Peripheral vessel	√	√	
▪ Musculo-skeletal (conventional)	√	√	
▪ Musculo-skeletal (superficial)	√	√	
▪ Neonatal cephalic	√	√	
▪ Adult cephalic	√	√	
Frequencies Supported:	√ (1.0MHZ~18MHz)	√ (1.0MHZ~18MHz)	√ (2.0MHz~17MHz)
Modes:			
▪ B	√	√	
▪ M	√	√	
▪ PWD (Pulsed Wave Doppler)	√	√	
▪ CWD (Continuous Wave Doppler)	√	√	
▪ PW DTI (Doppler Tissue Image)	√	√	
▪ Color Doppler	√	√	
▪ Power Doppler	√	√	
▪ Combined (BMDC)	√	√	
Features:			
▪ Harmonic imaging	√	√	
▪ Panoramic imaging	√	√	
▪ Color Panoramic imaging	√	√	
▪ Auto TEQ	√	√	
▪ Cardiac Imaging physiological signal display	√	√	
▪ eSie OB	√	√	
▪ Compounding	√	√	
▪ Contrast imaging	√	√	
▪ Clarify	√	√	

Feature / Characteristic	ACUSON Sequoia This Submission	ACUSON Sequoia K# 200707 Predicate device	ACUSON S family S1000/S2000/S3000 K# 172162 Reference device
▪ Virtual Touch - Strain	√	√	
▪ syngo ® Velocity Vector Imaging	√	√	
▪ eSie Calc	√	√	
▪ Speed of Sound	√	√	
▪ Fusion	√	√	
▪ Virtual Touch – pSWE	√	√	
▪ Virtual Touch – SWE	√	√	
▪ UltraArt	√	√	
▪ Modality Compare	√	√	
▪ HD Zoom	√	√	
▪ Protocols	√	√	
▪ InFocus	√	√	
▪ Flash sequencing	√	√	
▪ Gesture control	√	√	
▪ TeamViewer	√	√	
▪ Motion Stabilized Persistence	√	√	
▪ DICOM	√	√	
▪ DICOM SR	√	√	
▪ Slow Flow Color Doppler State	√	√	
▪ Dynamic MultiHertz	√	√	
▪ 3D/4D Volume Imaging Mode	√		√ (fourSight™ 4D transducer technology)
Wireless	√	√	
Monitor: 21" FPD (OLED)	√	√	
Touch Screen: 15" adjustable Touch Screen	√	√	
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 have

been found to conform to applicable medical device safety standards. The systems comply with the following voluntary standards:

- IEC 62359:2010, Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields / This document and its separate amendments continue to be valid together with the consolidated version.
- Safety and EMC Requirements for Medical Equipment
  - AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
  - IEC 60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance / This document and its separate amendments continue to be valid together with the consolidated version
  - IEC 60601-1-2 Edition 4.0 2014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
  - IEC 60601-2-18: Edition 3.0 2009-08, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
  - IEC 60601-2-37 Edition 2.1 2015, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- ISO 10993-1 Fourth edition 2009-10-15, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]

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

Since the ACUSON Sequoia Diagnostic Ultrasound System uses 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 to 21 CFR 820 Quality System Regulation and ISO 13485:2016 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. Diagnostic ultrasound system has accumulated a long history of safe and effective performance. Therefore, it is the opinion of Siemens Medical Solutions USA, Inc. that the ACUSON Sequoia system is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.