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

August 15, 2019

Re: K191922
Trade/Device Name: ACUSON P200 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
Dated: July 17, 2019
Received: July 18, 2019

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); 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)*

K191922

Device Name

ACUSON P200 Diagnostic Ultrasound System

Indications for Use *(Describe)*

The ACUSON P200 ultrasound imaging system is intended for the following applications: Fetal, Abdominal, Pediatric, Small Parts, OB/GYN (useful for visualization of the ovaries, follicles, uterus, and other pelvic structures), Adult, Pediatric and Neonatal Cardiac, Pelvic, Neonatal Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures; fetal, abdominal, pediatric, small organ, neonatal cephalic, cardiac (adult, pediatric and neonatal), trans-esophageal, transrectal, transvaginal, peripheral vessel, musculoskeletal (conventional), musculoskeletal (superficial) 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)

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

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Department of Health and Human Services
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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 P200 Diagnostic Ultrasound System**

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

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	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	BMCD	
Neonatal Cephalic	P	P	P		P	P	BMCD	
Adult Cephalic								
Cardiac	P	P	P	P	P	P	BMCD	
Trans-esophageal	P	P	P	P	P	P	BMCD	
Transrectal	P	P	P		P	P	BMCD	
Transvaginal	P	P	P		P	P	BMCD	
Transurethral								
Intravascular								
Peripheral vessel (Note 2)	P	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 FDA K180067; K180039; K187357

Note 1 For example: Breast, Thyroid, Testis
Note 2 For example: Carotid, Arterial, Venous

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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							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	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 (Note 2)								
Laparoscopic								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Other (specify)								

N = new indication; P = previously cleared by FDA K180067

Note 1 For example: Breast, Thyroid, Testis
Note 2 For example: Carotid, Arterial, Venous

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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							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	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								
Cardiac	P	P	P	P	P	P	BMCD	
Trans-esophageal								
Transrectal								
Transvaginal								
Transurethral								
Intravascular								
Peripheral vessel (Note 2)								
Laparoscopic								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Other (specify)								

N = new indication; P = previously cleared by FDA K180067

Note 1 For example: Breast, Thyroid, Testis
Note 2 For example: Carotid, Arterial, Venous

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

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	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								
Adult Cephalic								
Cardiac	P	P	P	P	P	P	BMCD	
Trans-esophageal								
Transrectal								
Transvaginal								
Transurethral								
Intravascular								
Peripheral vessel (Note 2)								
Laparoscopic								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Other (specify)								

N = new indication; P = previously cleared by FDA K180067

Note 1 For example: Breast, Thyroid, Testis
Note 2 For example: Carotid, Arterial, Venous

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

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	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	P	P	P		P	P	BMCD	
Adult Cephalic								
Cardiac	P	P	P	P	P	P	BMCD	
Trans-esophageal								
Transrectal								
Transvaginal								
Transurethral								
Intravascular								
Peripheral vessel (Note 2)								
Laparoscopic								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Other (specify)								

N = new indication; P = previously cleared by FDA K183575

Note 1 For example: Breast, Thyroid, Testis
Note 2 For example: Carotid, Arterial, Venous

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

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	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 (Note 2)								
Laparoscopic								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Other (specify)								

N = new indication; P = previously cleared by FDA K183575

Note 1 For example: Breast, Thyroid, Testis
Note 2 For example: Carotid, Arterial, Venous

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

N = new indication; P = previously cleared by FDA K183575

Note 1 For example: Breast, Thyroid, Testis
Note 2 For example: Carotid, Arterial, Venous

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

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	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								
Adult Cephalic								
Cardiac								
Trans-esophageal								
Transrectal								
Transvaginal								
Transurethral								
Intravascular								
Peripheral vessel (Note 2)	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 FDA K180067

Note 1 For example: Breast, Thyroid, Testis
Note 2 For example: Carotid, Arterial, Venous

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

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	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 (Note 2)	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 FDA K180067

Note 1 For example: Breast, Thyroid, Testis
Note 2 For example: Carotid, Arterial, Venous

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

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	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 (Note 2)								
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 FDA K180067

Note 1 For example: Breast, Thyroid, Testis
Note 2 For example: Carotid, Arterial, Venous

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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							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	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 (Note 2)								
Laparoscopic								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Other (specify)								

N = new indication; P = previously cleared by FDA K180067

Note 1 For example: Breast, Thyroid, Testis
Note 2 For example: Carotid, Arterial, Venous

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

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	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 (Note 2)								
Laparoscopic								
Musculo-skeletal Conventional	P	P	P		P	P	BMCD	
Musculo-skeletal Superficial								
Other (specify)								

N = new indication; P = previously cleared by FDA K180067

Note 1 For example: Breast, Thyroid, Testis
Note 2 For example: Carotid, Arterial, Venous

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

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	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 (Note 2)								
Laparoscopic								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Other (specify)								

N = new indication; P = previously cleared by FDA K180067

Note 1 For example: Breast, Thyroid, Testis
Note 2 For example: Carotid, Arterial, Venous

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

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

N = new indication; P = previously cleared by FDA K183575

Note 1 For example: Breast, Thyroid, Testis
Note 2 For example: Carotid, Arterial, Venous

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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: August 1, 2019

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

Contact Person:
HyunJung Lee
Tel: (425) 281-5061

2. Device Name: ACUSON P200 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

Manufacturing Site:
Siemens Healthineers Ltd.
2nd ~ 3rd Floor, 143, Sunhwan-ro, Jungwon-gu, Seongnam-si,
Gyeonggi-do, Republic of Korea

3. Legally Marketed Predicate Devices

The ACUSON P200 Diagnostic Ultrasound System is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to the company's own ACUSON X800 (K180067) which is the primary predicate device.

The additional predicates are the indications for Neonatal Cephalic and Trans-esophageal uses which are cleared under ACUSON S3000 (K183575) and eSie Left Heart, eSie Measure, eSie Follicle and Stress Eco under ACUSON Juniper (K180039) as described in the table of section 6 Summary of Technological Characteristics.

4. Device Description

The ACUSON P200 Diagnostic Ultrasound System is a multi-purpose mobile, software controlled, diagnostic ultrasound system with an on-screen display of thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to transmit and receive ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Color M Mode, Doppler Tissue Mode, Amplitude Doppler Mode, a combination of modes and Harmonic Imaging on a Display.

5. Intended Use

The ACUSON P200 ultrasound imaging system is intended for the following applications: Fetal, Abdominal, Pediatric, Small Parts, OB/GYN (useful for visualization of the ovaries, follicles, uterus, and other pelvic structures), Adult, Pediatric and Neonatal Cardiac, Pelvic, Neonatal Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides the ability to measure anatomical structures; fetal, abdominal, pediatric, small organ, neonatal cephalic, cardiac (adult, pediatric and neonatal), trans-esophageal, transrectal, transvaginal, peripheral vessel, musculoskeletal (conventional), musculoskeletal (superficial) 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 ACUSON P200 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 X800 (K180067), ACUSON Juniper (K180039) and ACUSON S3000 (K183575) with regards to both intended use and technological characteristics. Both the subject ultrasound system and the predicate ultrasound systems function in the same manner as all diagnostic ultrasound systems and transducers.

The foundation of the ACUSON P200 is the ACUSON X800 with features and transducers integrated with the ACUSON X800 hardware and the ACUSON P200 reuse software developed for X800 mainly as well as some transducers from Juniper and S3000 with a connector.

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

Feature / Characteristic	ACUSON P200 Subject device	ACUSON X800 K180067	ACUSON Juniper K1180039	ACUSON S3000 K183575
Indications for Use:				
▪ Fetal	√	√		
▪ Abdominal	√	√		
▪ Pediatric	√	√		
▪ Small Organ	√	√		
▪ Cardiac	√	√		
▪ Neonatal Cephalic	√			√
▪ Trans-esophageal	√			√
▪ Transrectal	√	√		
▪ Transvaginal	√	√		
▪ Peripheral vessel	√	√		
▪ Musculo-skeletal (conventional)	√	√		

Feature / Characteristic	ACUSON P200 Subject device	ACUSON X800 K180067	ACUSON Juniper K1180039	ACUSON S3000 K183575
▪ Musculo-skeletal (superficial)	√	√		
Frequencies Supported:	√ (1.0MHZ~18MHz)	√ (1.0MHZ~18MHz)		
Modes:				
▪ B	√	√		
▪ M	√	√		
▪ PWD (Pulsed Wave Doppler)	√	√		
▪ CWD (Continuous Wave Doppler)	√	√		
▪ PW DTI (Doppler Tissue Image)	√	√		
▪ Color Doppler	√	√		
▪ Power Doppler	√	√		
▪ Combined (BMDC)	√	√		
Features:				
▪ Harmonics	√	√		
▪ Compounding	√	√		
▪ UltraArt Universal Image processing	√	√		
▪ Tissue Equalization (TEQ)	√	√		
▪ Biopsy	√	√		
▪ Clarify	√	√		
▪ Cardiac Imaging	√	√		
▪ Speed of Sound	√	√		
▪ Protocols	√	√		
▪ DICOM	√	√		
▪ eSie Calcs	√	√		
▪ Wireless	√	√		
▪ Virtual Touch Strain Imaging	√	√		
▪ Virtual Touch Point Shear Wave (VTQ)	√	√		
▪ Virtual Touch Shear Wave (VTIQ)	√	√		
▪ Contrast Agent Imaging	√	√		
▪ eSie OB	√	√		
▪ eSie Left Heart	√		√	
▪ eSie Measure	√		√	
▪ eSie Follicle	√		√	
▪ Panoramic Imaging	√	√		
▪ Stress Echo	√		√	
▪ Syngo Velocity Vector Imaging (VVI)	√	√		
▪ eSieLink	√	√		
▪ DICOM SR	√	√		
Monitor (OLED)	√ (22”)	√ (21”)		

Feature / Characteristic	ACUSON P200 Subject device	ACUSON X800 K180067	ACUSON Juniper K1180039	ACUSON S3000 K183575
Touch Screen: adjustable display	√ (13.3")	√ (15")		
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:

- AIUM/NEMA UD-3:2004, Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2:2004 (R2009), Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3
- 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 P200 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 P200 system is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.