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

February 5, 2018

Re: K180039
Trade/Device Name: ACUSON P600 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: January 3, 2018
Received: January 5, 2018

Dear Mark Job:

This letter corrects our substantially equivalent letter of February 1, 2018.
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 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K180039

Device Name
ACUSON P600 Diagnostic Ultrasound System

Indications for Use *(Describe)*
The ACUSON P600 ultrasound imaging system is intended for the following applications: Vascular, Abdominal, Neonatal, Echocardiographical, Pediatric, Small Parts, Musculoskeletal, Obstetrical, Gynecological, Intraoperative, and Urological applications using different ultrasound transducers for different applications.
The system also provides the ability to measure anatomical structures and provides analysis packages that provide information used by a physician for clinical diagnosis purposes.
Ultrasound is used as an imaging aid, but may have further restrictions specific to in-vitro fertilization (IVF), chorionic villus sampling (CVS), and percutaneous umbilical cord blood sampling (PUBS) procedures. Observe local laws and regulations.

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 Society of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Medicine."

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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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **ACUSON P600™ Diagnostic Ultrasound System**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	2D (B)	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Abdominal (Note 1)	N	N	N		N	N	BCDM	
Obstetrics (Note 2)	N	N	N		N	N	BCDM	
Gynecology (Note 3)	N	N	N		N	N	BCDM	
Small Parts (Note 4)	N	N	N		N	N	BCDM	
Pediatric (Note 5)	N	N	N	N	N	N	BCDM	
Neonatal (Note 6)	N	N	N	N	N	N	BCDM	
Vascular (Note 7)	N	N	N	N	N	N	BCDM	
Urology (Note 8)	N	N	N		N	N	BCDM	
Echocardiography (Note 9)	N	N	N	N	N	N	BCDM	
Musculoskeletal (Note 10)	N	N	N		N	N	BCDM	
Intraoperative (Note 11)	N	N	N		N	N	BCDM	

N = new indication; P = previously cleared

Note 1	Abdominal (Abdominal, Renal, Bowel, Focused Assessment with Sonography for Trauma, Lung)
Note 2	Obstetrics (Obstetrics, Early Obstetrics, Fetal Echocardiography, Advanced Obstetrics)
Note 3	Gynecology (Gynecology, Pelvic Floor)
Note 4	Small Parts (Breast, Testicles, Penile, Thyroid)
Note 5	Pediatric (Pediatric Hip Joint, Pediatric Abdomen)
Note 6	Neonatal (Neonatal Head)
Note 7	Vascular (Carotid, Peripheral Venous, Peripheral Arterials, Transcranial Doppler)
Note 8	Urology (Pelvis, Prostate)
Note 9	Echocardiography (Adult Echocardiography, Pediatric Echocardiography, Neonatal Echocardiography)
Note 10	Musculoskeletal (Spine, Musculoskeletal, Digital, Nerve)
Note 11	Intraoperative (Intraoperative Abdomen, Intraoperative Vascular)

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

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

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **5C1 for ACUSON P600™ Diagnostic Ultrasound System**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	2D (B)	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Abdominal (Note 1)	N	N	N		N	N	BCDM	
Obstetrics (Note 2)	N	N	N		N	N	BCDM	
Gynecology (Note 3)	N	N	N		N	N	BCDM	
Small Parts (Note 4)								
Pediatric (Note 5)								
Neonatal (Note 6)								
Vascular (Note 7)	N	N	N		N	N	BCDM	
Urology (Note 8)	N	N	N		N	N	BCDM	
Echocardiography (Note 9)								
Musculoskeletal (Note 10)	N	N	N		N	N	BCDM	
Intraoperative (Note 11)								

N = new indication; P = previously cleared

Note 1	Abdominal (Abdominal, Renal, Bowel, Focused Assessment with Sonography for Trauma, Lung)
Note 2	Obstetrics (Obstetrics, Early Obstetrics, Fetal Echocardiography, Advanced Obstetrics)
Note 3	Gynecology (Gynecology, Pelvic Floor)
Note 4	Small Parts (Breast, Testicles, Penile, Thyroid)
Note 5	Pediatric (Pediatric Hip Joint, Pediatric Abdomen)
Note 6	Neonatal (Neonatal Head)
Note 7	Vascular (Carotid, Peripheral Venous, Peripheral Arterials, Transcranial Doppler)
Note 8	Urology (Pelvis, Prostate)
Note 9	Echocardiography (Adult Echocardiography, Pediatric Echocardiography, Neonatal Echocardiography)
Note 10	Musculoskeletal (Spine, Musculoskeletal, Digital, Nerve)
Note 11	Intraoperative (Intraoperative Abdomen, Intraoperative Vascular)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **5P1 for ACUSON P600™ Diagnostic Ultrasound System**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	2D (B)	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Abdominal (Note 1)	N	N	N		N	N	BCDM	
Obstetrics (Note 2)								
Gynecology (Note 3)								
Small Parts (Note 4)								
Pediatric (Note 5)								
Neonatal (Note 6)								
Vascular (Note 7)	N	N	N		N	N	BCDM	
Urology (Note 8)								
Echocardiography (Note 9)	N	N	N	N	N	N	BCDM	
Musculoskeletal (Note 10)								
Intraoperative (Note 11)								

N = new indication; P = previously cleared

Note 1	Abdominal (Abdominal, Renal, Bowel, Focused Assessment with Sonography for Trauma, Lung)
Note 2	Obstetrics (Obstetrics, Early Obstetrics, Fetal Echocardiography, Advanced Obstetrics)
Note 3	Gynecology (Gynecology, Pelvic Floor)
Note 4	Small Parts (Breast, Testicles, Penile, Thyroid)
Note 5	Pediatric (Pediatric Hip Joint, Pediatric Abdomen)
Note 6	Neonatal (Neonatal Head)
Note 7	Vascular (Carotid, Peripheral Venous, Peripheral Arterials, Transcranial Doppler)
Note 8	Urology (Pelvis, Prostate)
Note 9	Echocardiography (Adult Echocardiography, Pediatric Echocardiography, Neonatal Echocardiography)
Note 10	Musculoskeletal (Spine, Musculoskeletal, Digital, Nerve)
Note 11	Intraoperative (Intraoperative Abdomen, Intraoperative Vascular)

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

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **11L4 for ACUSON P600™ Diagnostic Ultrasound System**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	2D (B)	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Abdominal (Note 1)	N	N	N		N	N	BCDM	
Obstetrics (Note 2)	N	N	N		N	N	BCDM	
Gynecology (Note 3)								
Small Parts (Note 4)	N	N	N		N	N	BCDM	
Pediatric (Note 5)	N	N	N		N	N	BCDM	
Neonatal (Note 6)								
Vascular (Note 7)	N	N	N		N	N	BCDM	
Urology (Note 8)								
Echocardiography (Note 9)								
Musculoskeletal (Note 10)	N	N	N		N	N	BCDM	
Intraoperative (Note 11)								

N = new indication; P = previously cleared

Note 1	Abdominal (Abdominal, Renal, Bowel, Focused Assessment with Sonography for Trauma, Lung)
Note 2	Obstetrics (Obstetrics, Early Obstetrics, Fetal Echocardiography, Advanced Obstetrics)
Note 3	Gynecology (Gynecology, Pelvic Floor)
Note 4	Small Parts (Breast, Testicles, Penile, Thyroid)
Note 5	Pediatric (Pediatric Hip Joint, Pediatric Abdomen)
Note 6	Neonatal (Neonatal Head)
Note 7	Vascular (Carotid, Peripheral Venous, Peripheral Arterials, Transcranial Doppler)
Note 8	Urology (Pelvis, Prostate)
Note 9	Echocardiography (Adult Echocardiography, Pediatric Echocardiography, Neonatal Echocardiography)
Note 10	Musculoskeletal (Spine, Musculoskeletal, Digital, Nerve)
Note 11	Intraoperative (Intraoperative Abdomen, Intraoperative Vascular)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **12L3 for ACUSON P600™ Diagnostic Ultrasound System**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	2D (B)	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Abdominal (Note 1)	N	N	N		N	N	BCDM	
Obstetrics (Note 2)	N	N	N		N	N	BCDM	
Gynecology (Note 3)								
Small Parts (Note 4)	N	N	N		N	N	BCDM	
Pediatric (Note 5)	N	N	N		N	N	BCDM	
Neonatal (Note 6)								
Vascular (Note 7)	N	N	N		N	N	BCDM	
Urology (Note 8)								
Echocardiography (Note 9)								
Musculoskeletal (Note 10)	N	N	N		N	N	BCDM	
Intraoperative (Note 11)								

N = new indication; P = previously cleared

Note 1	Abdominal (Abdominal, Renal, Bowel, Focused Assessment with Sonography for Trauma, Lung)
Note 2	Obstetrics (Obstetrics, Early Obstetrics, Fetal Echocardiography, Advanced Obstetrics)
Note 3	Gynecology (Gynecology, Pelvic Floor)
Note 4	Small Parts (Breast, Testicles, Penile, Thyroid)
Note 5	Pediatric (Pediatric Hip Joint, Pediatric Abdomen)
Note 6	Neonatal (Neonatal Head)
Note 7	Vascular (Carotid, Peripheral Venous, Peripheral Arterials, Transcranial Doppler)
Note 8	Urology (Pelvis, Prostate)
Note 9	Echocardiography (Adult Echocardiography, Pediatric Echocardiography, Neonatal Echocardiography)
Note 10	Musculoskeletal (Spine, Musculoskeletal, Digital, Nerve)
Note 11	Intraoperative (Intraoperative Abdomen, Intraoperative Vascular)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **16L4 for ACUSON P600™ Diagnostic Ultrasound System**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	2D (B)	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Abdominal (Note 1)	N	N	N		N	N	BCDM	
Obstetrics (Note 2)								
Gynecology (Note 3)								
Small Parts (Note 4)	N	N	N		N	N	BCDM	
Pediatric (Note 5)	N	N	N		N	N	BCDM	
Neonatal (Note 6)								
Vascular (Note 7)	N	N	N		N	N	BCDM	
Urology (Note 8)								
Echocardiography (Note 9)								
Musculoskeletal (Note 10)	N	N	N		N	N	BCDM	
Intraoperative (Note 11)								

N = new indication; P = previously cleared

Note 1	Abdominal (Abdominal, Renal, Bowel, Focused Assessment with Sonography for Trauma, Lung)
Note 2	Obstetrics (Obstetrics, Early Obstetrics, Fetal Echocardiography, Advanced Obstetrics)
Note 3	Gynecology (Gynecology, Pelvic Floor)
Note 4	Small Parts (Breast, Testicles, Penile, Thyroid)
Note 5	Pediatric (Pediatric Hip Joint, Pediatric Abdomen)
Note 6	Neonatal (Neonatal Head)
Note 7	Vascular (Carotid, Peripheral Venous, Peripheral Arterials, Transcranial Doppler)
Note 8	Urology (Pelvis, Prostate)
Note 9	Echocardiography (Adult Echocardiography, Pediatric Echocardiography, Neonatal Echocardiography)
Note 10	Musculoskeletal (Spine, Musculoskeletal, Digital, Nerve)
Note 11	Intraoperative (Intraoperative Abdomen, Intraoperative Vascular)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **18H5 for ACUSON P600™ Diagnostic Ultrasound System**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	2D (B)	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Abdominal (Note 1)								
Obstetrics (Note 2)								
Gynecology (Note 3)								
Small Parts (Note 4)	N	N	N		N	N	BCDM	
Pediatric (Note 5)								
Neonatal (Note 6)								
Vascular (Note 7)	N	N	N		N	N	BCDM	
Urology (Note 8)								
Echocardiography (Note 9)								
Musculoskeletal (Note 10)	N	N	N		N	N	BCDM	
Intraoperative (Note 11)	N	N	N		N	N	BCDM	

N = new indication; P = previously cleared

Note 1	Abdominal (Abdominal, Renal, Bowel, Focused Assessment with Sonography for Trauma, Lung)
Note 2	Obstetrics (Obstetrics, Early Obstetrics, Fetal Echocardiography, Advanced Obstetrics)
Note 3	Gynecology (Gynecology, Pelvic Floor)
Note 4	Small Parts (Breast, Testicles, Penile, Thyroid)
Note 5	Pediatric (Pediatric Hip Joint, Pediatric Abdomen)
Note 6	Neonatal (Neonatal Head)
Note 7	Vascular (Carotid, Peripheral Venous, Peripheral Arterials, Transcranial Doppler)
Note 8	Urology (Pelvis, Prostate)
Note 9	Echocardiography (Adult Echocardiography, Pediatric Echocardiography, Neonatal Echocardiography)
Note 10	Musculoskeletal (Spine, Musculoskeletal, Digital, Nerve)
Note 11	Intraoperative (Intraoperative Abdomen, Intraoperative Vascular)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **9VE3 for ACUSON P600™ Diagnostic Ultrasound System**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	2D (B)	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Abdominal (Note 1)								
Obstetrics (Note 2)	N	N	N		N	N	BCDM	
Gynecology (Note 3)	N	N	N		N	N	BCDM	
Small Parts (Note 4)								
Pediatric (Note 5)								
Neonatal (Note 6)								
Vascular (Note 7)								
Urology (Note 8)								
Echocardiography (Note 9)								
Musculoskeletal (Note 10)								
Intraoperative (Note 11)								

N = new indication; P = previously cleared

Note 1	Abdominal (Abdominal, Renal, Bowel, Focused Assessment with Sonography for Trauma, Lung)
Note 2	Obstetrics (Obstetrics, Early Obstetrics, Fetal Echocardiography, Advanced Obstetrics)
Note 3	Gynecology (Gynecology, Pelvic Floor)
Note 4	Small Parts (Breast, Testicles, Penile, Thyroid)
Note 5	Pediatric (Pediatric Hip Joint, Pediatric Abdomen)
Note 6	Neonatal (Neonatal Head)
Note 7	Vascular (Carotid, Peripheral Venous, Peripheral Arterials, Transcranial Doppler)
Note 8	Urology (Pelvis, Prostate)
Note 9	Echocardiography (Adult Echocardiography, Pediatric Echocardiography, Neonatal Echocardiography)
Note 10	Musculoskeletal (Spine, Musculoskeletal, Digital, Nerve)
Note 11	Intraoperative (Intraoperative Abdomen, Intraoperative Vascular)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **8VC3 for ACUSON P600™ Diagnostic Ultrasound System**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	2D (B)	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Abdominal (Note 1)	N	N	N		N	N	BCDM	
Obstetrics (Note 2)	N	N	N		N	N	BCDM	
Gynecology (Note 3)	N	N	N		N	N	BCDM	
Small Parts (Note 4)								
Pediatric (Note 5)								
Neonatal (Note 6)								
Vascular (Note 7)								
Urology (Note 8)								
Echocardiography (Note 9)								
Musculoskeletal (Note 10)								
Intraoperative (Note 11)								

N = new indication; P = previously cleared

Note 1	Abdominal (Abdominal, Renal, Bowel, Focused Assessment with Sonography for Trauma, Lung)
Note 2	Obstetrics (Obstetrics, Early Obstetrics, Fetal Echocardiography, Advanced Obstetrics)
Note 3	Gynecology (Gynecology, Pelvic Floor)
Note 4	Small Parts (Breast, Testicles, Penile, Thyroid)
Note 5	Pediatric (Pediatric Hip Joint, Pediatric Abdomen)
Note 6	Neonatal (Neonatal Head)
Note 7	Vascular (Carotid, Peripheral Venous, Peripheral Arterials, Transcranial Doppler)
Note 8	Urology (Pelvis, Prostate)
Note 9	Echocardiography (Adult Echocardiography, Pediatric Echocardiography, Neonatal Echocardiography)
Note 10	Musculoskeletal (Spine, Musculoskeletal, Digital, Nerve)
Note 11	Intraoperative (Intraoperative Abdomen, Intraoperative Vascular)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **10MC3 for ACUSON P600™ Diagnostic Ultrasound System**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	2D (B)	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Abdominal (Note 1)								
Obstetrics (Note 2)	N	N	N		N	N	BCDM	
Gynecology (Note 3)	N	N	N		N	N	BCDM	
Small Parts (Note 4)								
Pediatric (Note 5)								
Neonatal (Note 6)								
Vascular (Note 7)								
Urology (Note 8)	N	N	N		N	N	BCDM	
Echocardiography (Note 9)								
Musculoskeletal (Note 10)								
Intraoperative (Note 11)								

N = new indication; P = previously cleared

Note 1	Abdominal (Abdominal, Renal, Bowel, Focused Assessment with Sonography for Trauma, Lung)
Note 2	Obstetrics (Obstetrics, Early Obstetrics, Fetal Echocardiography, Advanced Obstetrics)
Note 3	Gynecology (Gynecology, Pelvic Floor)
Note 4	Small Parts (Breast, Testicles, Penile, Thyroid)
Note 5	Pediatric (Pediatric Hip Joint, Pediatric Abdomen)
Note 6	Neonatal (Neonatal Head)
Note 7	Vascular (Carotid, Peripheral Venous, Peripheral Arterials, Transcranial Doppler)
Note 8	Urology (Pelvis, Prostate)
Note 9	Echocardiography (Adult Echocardiography, Pediatric Echocardiography, Neonatal Echocardiography)
Note 10	Musculoskeletal (Spine, Musculoskeletal, Digital, Nerve)
Note 11	Intraoperative (Intraoperative Abdomen, Intraoperative Vascular)

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

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **9MC3 for ACUSON P600™ Diagnostic Ultrasound System**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	2D (B)	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Abdominal (Note 1)								
Obstetrics (Note 2)	N	N	N		N	N	BCDM	
Gynecology (Note 3)	N	N	N		N	N	BCDM	
Small Parts (Note 4)								
Pediatric (Note 5)								
Neonatal (Note 6)								
Vascular (Note 7)								
Urology (Note 8)	N	N	N		N	N	BCDM	
Echocardiography (Note 9)								
Musculoskeletal (Note 10)								
Intraoperative (Note 11)								

N = new indication; P = previously cleared

Note 1	Abdominal (Abdominal, Renal, Bowel, Focused Assessment with Sonography for Trauma, Lung)
Note 2	Obstetrics (Obstetrics, Early Obstetrics, Fetal Echocardiography, Advanced Obstetrics)
Note 3	Gynecology (Gynecology, Pelvic Floor)
Note 4	Small Parts (Breast, Testicles, Penile, Thyroid)
Note 5	Pediatric (Pediatric Hip Joint, Pediatric Abdomen)
Note 6	Neonatal (Neonatal Head)
Note 7	Vascular (Carotid, Peripheral Venous, Peripheral Arterials, Transcranial Doppler)
Note 8	Urology (Pelvis, Prostate)
Note 9	Echocardiography (Adult Echocardiography, Pediatric Echocardiography, Neonatal Echocardiography)
Note 10	Musculoskeletal (Spine, Musculoskeletal, Digital, Nerve)
Note 11	Intraoperative (Intraoperative Abdomen, Intraoperative Vascular)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **10V4 for ACUSON P600™ Diagnostic Ultrasound System**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	2D (B)	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Abdominal (Note 1)								
Obstetrics (Note 2)								
Gynecology (Note 3)								
Small Parts (Note 4)								
Pediatric (Note 5)	P	P	P		P	P	BCDM	
Neonatal (Note 6)	P	P	P		P	P	BCDM	
Vascular (Note 7)								
Urology (Note 8)								
Echocardiography (Note 9)	P	P	P	P	P	P	BCDM	
Musculoskeletal (Note 10)								
Intraoperative (Note 11)								

N = new indication; P = previously cleared (K163635)

Note 1	Abdominal (Abdominal, Renal, Bowel, Focused Assessment with Sonography for Trauma, Lung)
Note 2	Obstetrics (Obstetrics, Early Obstetrics, Fetal Echocardiography, Advanced Obstetrics)
Note 3	Gynecology (Gynecology, Pelvic Floor)
Note 4	Small Parts (Breast, Testicles, Penile, Thyroid)
Note 5	Pediatric (Pediatric Hip Joint, Pediatric Abdomen)
Note 6	Neonatal (Neonatal Head)
Note 7	Vascular (Carotid, Peripheral Venous, Peripheral Arterials, Transcranial Doppler)
Note 8	Urology (Pelvis, Prostate)
Note 9	Echocardiography (Adult Echocardiography, Pediatric Echocardiography, Neonatal Echocardiography)
Note 10	Musculoskeletal (Spine, Musculoskeletal, Digital, Nerve)
Note 11	Intraoperative (Intraoperative Abdomen, Intraoperative Vascular)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **8V4 for ACUSON P600™ Diagnostic Ultrasound System**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	2D (B)	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Abdominal (Note 1)								
Obstetrics (Note 2)								
Gynecology (Note 3)								
Small Parts (Note 4)								
Pediatric (Note 5)	N	N	N	N	N	N	BCDM	
Neonatal (Note 6)	N	N	N	N	N	N	BCDM	
Vascular (Note 7)								
Urology (Note 8)								
Echocardiography (Note 9)	N	N	N	N	N	N	BCDM	
Musculoskeletal (Note 10)								
Intraoperative (Note 11)								

N = new indication; P = previously cleared

Note 1	Abdominal (Abdominal, Renal, Bowel, Focused Assessment with Sonography for Trauma, Lung)
Note 2	Obstetrics (Obstetrics, Early Obstetrics, Fetal Echocardiography, Advanced Obstetrics)
Note 3	Gynecology (Gynecology, Pelvic Floor)
Note 4	Small Parts (Breast, Testicles, Penile, Thyroid)
Note 5	Pediatric (Pediatric Hip Joint, Pediatric Abdomen)
Note 6	Neonatal (Neonatal Head)
Note 7	Vascular (Carotid, Peripheral Venous, Peripheral Arterials, Transcranial Doppler)
Note 8	Urology (Pelvis, Prostate)
Note 9	Echocardiography (Adult Echocardiography, Pediatric Echocardiography, Neonatal Echocardiography)
Note 10	Musculoskeletal (Spine, Musculoskeletal, Digital, Nerve)
Note 11	Intraoperative (Intraoperative Abdomen, Intraoperative Vascular)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **7C2 for ACUSON P600™ Diagnostic Ultrasound System**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	2D (B)	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Abdominal (Note 1)	N	N	N		N	N	BCDM	
Obstetrics (Note 2)	N	N	N		N	N	BCDM	
Gynecology (Note 3)	N	N	N		N	N	BCDM	
Small Parts (Note 4)								
Pediatric (Note 5)	N	N	N		N	N	BCDM	
Neonatal (Note 6)								
Vascular (Note 7)								
Urology (Note 8)	N	N	N		N	N	BCDM	
Echocardiography (Note 9)								
Musculoskeletal (Note 10)	N	N	N		N	N	BCDM	
Intraoperative (Note 11)								

N = new indication; P = previously cleared

Note 1	Abdominal (Abdominal, Renal, Bowel, Focused Assessment with Sonography for Trauma, Lung)
Note 2	Obstetrics (Obstetrics, Early Obstetrics, Fetal Echocardiography, Advanced Obstetrics)
Note 3	Gynecology (Gynecology, Pelvic Floor)
Note 4	Small Parts (Breast, Testicles, Penile, Thyroid)
Note 5	Pediatric (Pediatric Hip Joint, Pediatric Abdomen)
Note 6	Neonatal (Neonatal Head)
Note 7	Vascular (Carotid, Peripheral Venous, Peripheral Arterials, Transcranial Doppler)
Note 8	Urology (Pelvis, Prostate)
Note 9	Echocardiography (Adult Echocardiography, Pediatric Echocardiography, Neonatal Echocardiography)
Note 10	Musculoskeletal (Spine, Musculoskeletal, Digital, Nerve)
Note 11	Intraoperative (Intraoperative Abdomen, Intraoperative Vascular)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **11M3 for ACUSON P600™ Diagnostic Ultrasound System**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	2D (B)	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Abdominal (Note 1)								
Obstetrics (Note 2)								
Gynecology (Note 3)								
Small Parts (Note 4)								
Pediatric (Note 5)	N	N	N		N	N	BCDM	
Neonatal (Note 6)	N	N	N		N	N	BCDM	
Vascular (Note 7)	N	N	N		N	N	BCDM	
Urology (Note 8)								
Echocardiography (Note 9)	N	N	N		N	N	BCDM	
Musculoskeletal (Note 10)								
Intraoperative (Note 11)								

N = new indication; P = previously cleared

Note 1	Abdominal (Abdominal, Renal, Bowel, Focused Assessment with Sonography for Trauma, Lung)
Note 2	Obstetrics (Obstetrics, Early Obstetrics, Fetal Echocardiography, Advanced Obstetrics)
Note 3	Gynecology (Gynecology, Pelvic Floor)
Note 4	Small Parts (Breast, Testicles, Penile, Thyroid)
Note 5	Pediatric (Pediatric Hip Joint, Pediatric Abdomen)
Note 6	Neonatal (Neonatal Head)
Note 7	Vascular (Carotid, Peripheral Venous, Peripheral Arterials, Transcranial Doppler)
Note 8	Urology (Pelvis, Prostate)
Note 9	Echocardiography (Adult Echocardiography, Pediatric Echocardiography, Neonatal Echocardiography)
Note 10	Musculoskeletal (Spine, Musculoskeletal, Digital, Nerve)
Note 11	Intraoperative (Intraoperative Abdomen, Intraoperative Vascular)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **CW2 for ACUSON P600™ Diagnostic Ultrasound System**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	2D (B)	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Abdominal (Note 1)								
Obstetrics (Note 2)								
Gynecology (Note 3)								
Small Parts (Note 4)								
Pediatric (Note 5)								
Neonatal (Note 6)								
Vascular (Note 7)								
Urology (Note 8)								
Echocardiography (Note 9)				P				
Musculoskeletal (Note 10)								
Intraoperative (Note 11)								

N = new indication; P = previously cleared (K163635)

Note 1	Abdominal (Abdominal, Renal, Bowel, Focused Assessment with Sonography for Trauma, Lung)
Note 2	Obstetrics (Obstetrics, Early Obstetrics, Fetal Echocardiography, Advanced Obstetrics)
Note 3	Gynecology (Gynecology, Pelvic Floor)
Note 4	Small Parts (Breast, Testicles, Penile, Thyroid)
Note 5	Pediatric (Pediatric Hip Joint, Pediatric Abdomen)
Note 6	Neonatal (Neonatal Head)
Note 7	Vascular (Carotid, Peripheral Venous, Peripheral Arterials, Transcranial Doppler)
Note 8	Urology (Pelvis, Prostate)
Note 9	Echocardiography (Adult Echocardiography, Pediatric Echocardiography, Neonatal Echocardiography)
Note 10	Musculoskeletal (Spine, Musculoskeletal, Digital, Nerve)
Note 11	Intraoperative (Intraoperative Abdomen, Intraoperative Vascular)

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **CW5 for ACUSON P600™ Diagnostic Ultrasound System**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation							
	2D (B)	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Abdominal (Note 1)								
Obstetrics (Note 2)								
Gynecology (Note 3)								
Small Parts (Note 4)								
Pediatric (Note 5)								
Neonatal (Note 6)								
Vascular (Note 7)				P				
Urology (Note 8)								
Echocardiography (Note 9)				P				
Musculoskeletal (Note 10)								
Intraoperative (Note 11)								

N = new indication; P = previously cleared (K163635)

Note 1	Abdominal (Abdominal, Renal, Bowel, Focused Assessment with Sonography for Trauma, Lung)
Note 2	Obstetrics (Obstetrics, Early Obstetrics, Fetal Echocardiography, Advanced Obstetrics)
Note 3	Gynecology (Gynecology, Pelvic Floor)
Note 4	Small Parts (Breast, Testicles, Penile, Thyroid)
Note 5	Pediatric (Pediatric Hip Joint, Pediatric Abdomen)
Note 6	Neonatal (Neonatal Head)
Note 7	Vascular (Carotid, Peripheral Venous, Peripheral Arterials, Transcranial Doppler)
Note 8	Urology (Pelvis, Prostate)
Note 9	Echocardiography (Adult Echocardiography, Pediatric Echocardiography, Neonatal Echocardiography)
Note 10	Musculoskeletal (Spine, Musculoskeletal, Digital, Nerve)
Note 11	Intraoperative (Intraoperative Abdomen, Intraoperative Vascular)

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510(k) Summary

Date: August 31, 2017

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

Manufacturing Facility: Siemens Healthcare Ltd.
2nd -3rd floor, 143, Sunhwan-ro,
Jungwon-gu, Seongnam-si, Gyeonggi-do,
Republic of Korea

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

Device Name: ACUSON P600 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

A. Legally Marketed Predicate Devices

The ACUSON P600 Diagnostic Ultrasound System is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to our current products, the ACUSON X700 (K141846), ACUSON S2000 (K163635), ACUSON P500 (K163396) and ACUSON SC2000 (K170315).

B. Device Description

The ACUSON P600 Diagnostic Ultrasound System is a multi-purpose mobile, software controlled, diagnostic ultrasound systems with an on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to acquire harmonic 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 Image, Amplitude Doppler Mode, a combination of modes, or Harmonic Imaging and 3D Imaging, or Harmonic Imaging and 4D imaging on a Flat Panel Display.

C. Intended Use

The ACUSON P600 ultrasound imaging system is intended for the following applications: Vascular, Abdominal, Neonatal, Echocardiographical, Pediatric, Small Parts, Musculoskeletal, Obstetrical, Gynecological, Intraoperative, and Urological applications using different ultrasound transducers for different applications.

The system also provides the ability to measure anatomical structures and analysis packages that provide information that is used by a physician for clinical diagnosis purposes.

Ultrasound is used as an imaging aid, but may have further restrictions specific to in-vitro fertilization (IVF), chorionic villus sampling (CVS), and percutaneous umbilical cord blood sampling (PUBS) procedures. Observe local laws and regulations.

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 Society of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Medicine."

D. Substantial Equivalence

The ACUSON P600 Diagnostic Ultrasound System is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to our current products, the ACUSON X700 (K141846), ACUSON SC2000 (K170315), ACUSON S2000 (K163635) and ACUSON P500 (K163396). All systems transmit ultrasonic energy into patients, and then perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

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

	Predicate Device ACUSON X700 (K141846)	Predicate Device ACUSON SC2000 (K170315)	Predicate Device ACUSON S2000 (K163635)	Predicate Device ACUSON P500 (K163396)	Submission Device ACUSON P600
Indications for Use:					
▪ Abdominal (Abdominal, Renal, Bowel, Focused Assessment with Sonography for Trauma, Lung)	√	-	-	-	√
▪ Obstetrics (Obstetrics, Early Obstetrics, Fetal Echocardiography, Advanced Obstetrics)	√	-	-	-	√
▪ Gynecology (Gynecology, Pelvic Floor)	√	-	-	-	√
▪ Small Parts (Breast, Testicles, Penile, Thyroid)	√	-	-	-	√
▪ Pediatric (Pediatric Hip Joint, Pediatric Abdomen)	√	-	-	-	√
▪ Neonatal (Neonatal Head)	√	-	-	-	√
▪ Vascular (Carotid, Peripheral Venous, Peripheral Arterials, Transcranial Doppler)	√	-	-	-	√
▪ Urology (Pelvis, Prostate)	√	-	-	-	√
▪ Echocardiography (Adult Echocardiography, Pediatric Echocardiography, Neonatal Echocardiography)	√	-	-	-	√
▪ Musculoskeletal (Spine, Musculoskeletal, Digital, Nerve)	√	-	-	-	√
▪ Intraoperative (Intraoperative Abdomen, Intraoperative Vascular)	√	-	-	-	√
Modes:					
▪ 2D (Brightness mode)	√	-	-	-	√
▪ C (Color Flow Doppler)	√	-	-	-	√
▪ D (Doppler)	√	-	-	-	√

	Predicate Device ACUSON X700 (K141846)	Predicate Device ACUSON SC2000 (K170315)	Predicate Device ACUSON S2000 (K163635)	Predicate Device ACUSON P500 (K163396)	Submission Device ACUSON P600
▪ M (Motion Mode)	√	-	-	-	√
▪ CW (Continuous Waver Doppler)	√	-	-	-	√
Features:					
▪ DICOM (3.0 Connectivity, Worklist, MPPS)	√	-	-	-	√
▪ DICOM SR OB/GYN	√	-	-	-	√
▪ DICOM SR Cardiac	√	-	-	-	√
▪ DICOM SR Vascular	√	-	-	-	√
▪ syngo Arterial Health Package (AHP)	√	-	-	-	√
▪ syngo Auto Follicle	√	-	-	-	√
▪ syngo Auto OB	√	-	-	-	√
▪ eSie Left Heart (eSie LH)	-	√	-	-	√
▪ Stress Echo	√	-	-	-	√
▪ 3-Scape Imaging	-	-	√	-	√
▪ fourSight 4D	√	-	-	-	√
▪ Advanced fourSight 4D Imaging	-	-	√	-	√
▪ eSie Touch Elasticity Imaging	√	-	-	-	√
▪ eSie Measure Workflow Acceleration Package	-	-	-	√	√
▪ eSieScan Workflow Protocol	-	-	-	√	√
▪ Virtual Touch Quantification (VTQ)	-	-	√	-	√
▪ SieScape Panoramic Imaging	√	-	-	-	√
▪ Dynamic Tissue Contrast Enhancement (DTCE)	√	-	-	-	√
▪ Advanced SieClear (ASC)	√	-	-	-	√
▪ Clarify Vascular Enhancement (Clarify VE)	√	-	-	-	√
▪ eSieImage (TEQ/TGO)	-	-	√	-	√

	Predicate Device ACUSON X700 (K141846)	Predicate Device ACUSON SC2000 (K170315)	Predicate Device ACUSON S2000 (K163635)	Predicate Device ACUSON P500 (K163396)	Submission Device ACUSON P600
▪ Anatomical M-mode (AMM)	√	-	-	-	√
▪ HD Zoom (Res)	√	-	-	-	√
▪ Needle Visualization	-	-	-	√	√
▪ Tissue Harmonic Imaging (THI)	√	-	-	-	√
▪ Doppler Tissue Imaging (DTI)	√	-	-	-	√
▪ Custom Tissue Imaging (CTI)	-	-	√	-	√
▪ eSieCalcs	-	-	√	-	√
▪ Wireless	√	-	-	-	√
▪ Veterinary(VET) Imaging	√	-	-	-	√
▪ US Security (Virus Protection)	√	-	-	-	√

E. 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:

- ANSI/AAMI ES 60601-1, Safety Requirements for Medical Equipment
- 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
- IEC 60601-1-2
- IEC 60601-2-18
- IEC 60601-2-37
- ISO 10993-1
- ISO 14971

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

Since the ACUSON P600 Diagnostic Ultrasound System uses the same technology and principles as existing devices, clinical data is not required.

G. 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 13485:2003 quality system standards. The product is designed to conform to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. 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 P600 Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

The ACUSON P600 Diagnostic Ultrasound System is verified and validated according to the company’s design control process.