



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

SIEMENS MEDICAL SOLUTIONS USA, INC.
c/o Mr. MARK JOB
OFFICIAL CORRESPONDENT
1394 25TH STREET, NW
BUFFALO MN 55313

January 4, 2017

Re: K163396
Trade/Device Name: Acuson P500 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX, OBJ
Dated: December 1, 2016
Received: December 5, 2016

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



For

Robert Ochs
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K163396

Device Name

ACUSON P500 Ultrasound System

Indications for Use (Describe)

The ACUSON P500 ultrasound imaging system is intended for the following applications:

Fetal, Abdominal (including liver), Pediatric, Small Parts, Transcranial, OB/GYN(useful for visualization of the ovaries, follicles, uterus and other pelvic structures), Pelvic, Neonatal, Cardiac, IntraCardiac, Vascular(including Peripheral Vessel), Musculoskeletal, Superficial Musculoskeletal, and Urology applications.

The system also provides the ability to measure anatomical structures fetal, abdominal, small organ, transrectal, transvaginal, cardiovascular, peripheral vessel, musculoskeletal (conventional), and 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.

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 Imaging."

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

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.

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:
 Intended Use:

ACUSON P500™ Ultrasound System
 Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Specific (Tracks 11& 3)	Mode of Operation					Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
		B	M	PWD	CW/D					
Other (Track 1 Only)										
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	BMDC	Note 2, 3, 4, 11, 12, 16	
	Abdominal	P	P	P	P	P	P	BMDC	Note 2, 3, 4, 11, 12, 16	
	Intra-operative (Note 6)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ (Note 1)	P	P	P		P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16	
	Neonatal Cephalic				N					
	Adult Cephalic									
	Trans-rectal	P	P	P		P	P	BMDC	Note 2, 3, 4, 11, 12, 16	
Trans-vaginal	P	P	P		P	P	BMDC	Note 2, 3, 4, 11, 12, 16		
Trans-urethral										
Trans-esoph. (non-Card.)										
Musculo-skel. (Convent.)	P	P	P		P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16		
Musculo-skel. (Superfic)	P	P	P		P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16		
Intra -vascular										
Other (Specify)										
Cardiac	Cardiac Adult	P	P	P	P	P	P	BMDC	Note 2, 4, 6, 7, 8, 10, 12, 16	
	Cardiac Pediatric	N	N	N	N	N	N	BMDC	Note 2, 4, 6, 7, 10, 12, 16	
	Intra-vascular (Cardiac)									
	Trans-esophageal (Cardiac)									
	Intra-Cardiac	N	N	N	N	N	N	BMDC	Note 2, 4, 10, 12, 14, 15, 16	
Other (Specify)										
Peripheral Vessel	Peripheral vessel	P	P	P	N	P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16	
	Other (Specify)									

N = new indication; P = previously cleared

Note 1	For example: breast, testes, thyroid, prostate, etc. Dynamic TCE Technology Advanced SteClear eSteImage For example: abdominal, vascular (upper and lower)	Note 6	Stress Echo eSteMeasure eSteScan AHP DTI Panoramic 2D Imaging (SteScape) Clarity VE Needle Visualization Intracardiac Echocardiography (ICE) Imaging CARTOSOUND Communication Probe Saver
Note 2		Note 7	
Note 3		Note 8	
Note 4		Note 9	
Note 5		Note 10	

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

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **P4-2 Phased Array Transducer for use with:
 ACUSON P500™ Ultrasound System**

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

Clinical Application	Mode of Operation						Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
	B	M	PWD	CWD						
Other (Track1 Only)	Specific (Tracks:1& 3)									
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P	BMDC	Note 2, 4, 12, 16
	Abdominal	P	P	P	P	P	P	P	BMDC	Note 2, 4, 12, 16
	Intra-operative									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ (Note 1)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
Trans-urethral										
Trans-esoph. (non-Card.)										
Musculo-skel. (Convent.)										
Musculo-skel. (Superfic)										
Intra-vascular										
Other (Specify)										
Cardiac	Cardiac Adult	P	P	P	P	P	P	P	BMDC	Note 2, 4, 6, 7, 8, 10, 12, 16
	Cardiac Pediatric									
	Intra-vascular (Cardiac)									
	Trans-esophageal (Cardiac)									
	Intra-cardiac									
	Other (Specify)									
Peripheral Vessel	Peripheral Vessel (Note 5)									
	Other (Specify)									

N = new indication; P = previously cleared K150050

Note 1	For example: breast, testes, thyroid, prostate, etc. Dynamic TCE Technology Advanced SteClear eSteImage For example: abdominal, vascular (upper and lower)	Note 6	Stress Echo eSteMeasure eSteScan AHP DTI Panoramic 2D Imaging (SteScape) Needle Visualization Intracardiac Echocardiography (ICE) Imaging CARTOSOUND Communication Probe Saver
Note 2		Note 7	
Note 3		Note 8	
Note 4		Note 9	
Note 5		Note 10	

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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:

CH5-2 Curved Array Transducer for use with:
ACUSON P500™ Ultrasound System

Intended Use:

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

Clinical Application	Mode of Operation					Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
	B	M	PWD	CWD					
Other (Track1 Only)	Specific (Tracks1& 3)								
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	BMDC	Note 2, 3, 4, 11, 12, 16
	Abdominal	P	P	P		P	P	BMDC	Note 2, 3, 4, 11, 12, 16
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
Musculo-skel. (Convent.)	P	P	P		P	P	BMDC	Note 2, 3, 4, 11, 12, 16	
Musculo-skel. (Superfic)									
Intra-vascular									
Other (Specify)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel (Note 5)	P	P	P		P	P	BMDC	Note 2, 3, 4, 11, 12, 16
	Other (Specify)								

N = new indication; P = previously cleared K150050

Note 1	For example: breast, testes, thyroid, prostate, etc. Dynamic TCE Technology Advanced SteClear eSteImage For example: abdominal, vascular (upper and lower)	Note 6	Stress Echo eSteMeasure eSteScan AHP DTI Panoramic 2D Imaging (SteScape) Clarity VE Needle Visualization Intracardiac Echocardiography (ICE) Imaging CARTOSOUND Communication Probe Saver
Note 2		Note 7	
Note 3		Note 8	
Note 4		Note 9	
Note 5		Note 10	

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **VF10-5 Linear Array Transducer for use with:
 ACUSON P500™ Ultrasound System**

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

Clinical Application	Specific (Tracks:1& 3)	Mode of Operation				Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
		B	M	PWD	CWD				
Other (Track1 Only)									
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
Fetal Imaging & Other	Small Organ (Note 1)	P	P	P		P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)	P	P	P		P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel (Note 5)	P	P	P				BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16
	Other (Specify)								

N = new indication; P = previously cleared K150050

Note 1	For example: breast, testes, thyroid, prostate, etc. Dynamic TCE Technology Advanced SteClear eSteImage For example: abdominal, vascular (upper and lower)	Note 6	Stress Echo eSteMeasure eSteScan AHP DTI Panoramic 2D Imaging (SteScape) Needle Visualization Intracardiac Echocardiography (ICE) Imaging CARTOSOUND Communication Probe Saver
Note 2		Note 7	
Note 3		Note 8	
Note 4		Note 9	
Note 5		Note 10	

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

**EC9-4 Curved Array Transducer for use with:
 ACUSON P500™ Ultrasound System**

Intended Use:

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

Clinical Application	Specific (Tracks 1 & 3)	Mode of Operation				Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Other (Track 1 Only)	B	M	PWD	CWD					
Ophthalmic	Ophthalmic								
	Fetal	P	P	P		P	P	BMDC	Note 2, 3, 4, 11, 12, 16
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal Imaging & Other	Pediatric								
	Small Organ (Note 1)	P	P	P		P	P	BMDC	Note 2, 3, 4, 11, 12, 16
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	BMDC	Note 2, 3, 4, 11, 12, 16
	Trans-vaginal	P	P	P		P	P	BMDC	Note 2, 3, 4, 11, 12, 16
	Trans-urethral								
	Trans-esoph. (non-Card)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel (Note 5)								
	Other (Specify)								

N = new indication; P = previously cleared K150050

Note 1	For example: breast, testes, thyroid, prostate, etc.	Note 6	Stress Echo
Note 2	Dynamic TCE Technology	Note 7	eSieWearsure
Note 3	Advanced SieClear	Note 8	eSieScan
Note 4	eSieImage	Note 9	AHP
Note 5	For example: abdominal, vascular (upper and lower)	Note 10	DTI
		Note 11	Panoramic 2D Imaging (SieScape)
		Note 12	Clarity VE
		Note 13	Needle Visualization
		Note 14	Intracardiac Echocardiography (ICE) Imaging
		Note 15	CARTOSOUND Communication
		Note 16	Probe Saver

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **VF13-5 Linear Transducer for use with:
 ACUSON P500™ Ultrasound System**
 Intended Use: **Diagnostic imaging or fluid flow analysis of the human body as follows:**

Clinical Application	Mode of Operation					Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
	B	M	PWD	CWD					
Other (Track1 Only)									
Specific (Tracks 11&. 3)									
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal	Pediatric								
Imaging & Other	Small Organ (Note 1)	P	P	P		P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)	P	P	P		P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16
	Intra-vascular								
	Other (Specify)								
	Cardiac Adult								
	Cardiac Pediatric								
Intra-vascular (Cardiac)									
Trans-esophageal (Cardiac)									
Intra-cardiac									
Other (Specify)									
Peripheral vessel (Note 5)	P	P	P		P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16	
Other (Specify)									
Peripheral vessel (Note 5)									
Vessel									

N = new indication; P = previously cleared K150050

Note 1 For example: breast, testes, thyroid, prostate, etc.
 Note 2 Dynamic TCE Technology
 Note 3 Advanced SteClear
 Note 4 eSteImage
 Note 5 For example: abdominal, vascular (upper and lower)

Note 6 Stress Echo
 Note 7 eSteMeasure
 Note 8 eSteScan
 Note 9 AHP
 Note 10 DTI
 Note 11 Panoramic 2D Imaging (SteScape)
 Note 12 Clarify VE
 Note 13 Needle Visualization
 Note 14 Intracardiac Echocardiography (ICE) Imaging
 Note 15 CARTOSOUND Communication
 Note 16 Probe Saver

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: VF16-5 Transducer for use with:
ACUSON P500™ Ultrasound System

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

Clinical Application	Mode of Operation						Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
	Specific (Tracks:1& 3)	B	M	PWD	CWD					
Other (Track1 Only)										
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ (Note 1)	P	P	P			P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
Musculo-skel. (Convent.)										
Musculo-skel. (Superficial)	P	P	P			P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16	
Intra-vascular										
Other (Specify)										
Cardiac Adult										
Cardiac Pediatric										
Intra-vascular (Cardiac)										
Trans-esophageal (Cardiac)										
Intra-cardiac										
Other (Specify)										
Peripheral Vessel (Note 5)										
Other (Specify)										

N = new indication; P = previously cleared K141846

Note 1	For example: breast, testes, thyroid, prostate, etc. Dynamic TCE Technology Advanced SteClear eSteImage For example: abdominal, vascular (upper and lower)	Note 6	Stress Echo eSteMeasure eSteScan AHP DTI Panoramic 2D Imaging (SteScape) Clarity VE Needle Visualization Intracardiac Echocardiography (ICE) Imaging CARTOSOUND Communication Probe Saver
Note 2		Note 7	
Note 3		Note 8	
Note 4		Note 9	
Note 5		Note 10	

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: P8-4 Transducer for use with:
ACUSON P500™ Ultrasound System

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

Clinical Application	Mode of Operation							Other (Specify)		
	Other (Track1 Only)	Specific (Tracks 1& 3)	B	M	PWD	CWD	Color Doppler		Power Doppler	Combined (Specify)
Ophthalmic	Ophthalmic									
	Fetal									
	Abdominal	P	P	P			P	P	BMDC	Note 2, 4, 12, 16
	Intra-operative									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ (Note 1)									
	Neonatal Cephalic									
	Adult Cephalic									
Fetal Imaging & Other	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic)									
	Intra-vascular									
	Other (Specify)									
	Cardiac Adult									
	Cardiac Pediatric	P	P	P	P	P	P	P	BMDC	Note 2, 4, 6, 7, 10, 12, 16
Cardiac	Intra-vascular (Cardiac)									
	Trans-esophageal (Cardiac)									
	Intra-cardiac									
	Other (Specify)									
Peripheral Vessel	Peripheral Vessel (Note 5)									
	Other (Specify)									

N = new indication; P = previously cleared by K141846, K161787

Note 1	For example: breast, testes, thyroid, prostate, etc. Dynamic TCE Technology Advanced SteClear eSteImage For example: abdominal, vascular (upper and lower)	Note 6	Stress Echo eSteMeasure eSteScan AHP DTI Panoramic 2D Imaging (SteScape) Clarity VE Needle Visualization Intracardiac Echocardiography (ICE) Imaging CARTOSOUND Communication Probe Saver
Note 2		Note 7	
Note 3		Note 8	
Note 4		Note 9	
Note 5		Note 10	

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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:

L10-5v Transducer for use with:
ACUSON P500™ Ultrasound System

Intended Use:

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

Clinical Application	Specific (Tracks:1& 3)	Mode of Operation					Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
		B	M	PWD	CWD					
Other (Track1 Only)										
Ophthalmic	Ophthalmic									
	Fetal									
	Abdominal									
	Intra-operative									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
Fetal Imaging & Other	Small Organ (Note 1)	P	P	P		P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16	
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)	P	P	P		P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16	
	Musculo-skel. (Superfic)									
	Intra-vascular									
	Other (Specify)									
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intra-vascular (Cardiac)									
	Trans-esophageal (Cardiac)									
	Intra-cardiac									
	Other (Specify)									
Peripheral Vessel	Peripheral vessel (Note 5)	P	P	P		P	P	BMDC	Note 2, 3, 4, 9, 11, 12, 13, 16	
	Other (Specify)									

N = new indication; P = previously cleared K161787

Note 1	For example: breast, testes, thyroid, prostate, etc. Dynamic TCE Technology Advanced SteClear eSteImage For example: abdominal, vascular (upper and lower)	Note 6	Stress Echo eSteMeasure eSteScan AHP DTI Panoramic 2D Imaging (SteScape) Needle Visualization Intracardiac Echocardiography (ICE) Imaging CARTOSOUND Communication Probe Saver
Note 2		Note 7	
Note 3		Note 8	
Note 4		Note 9	
Note 5		Note 10	

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: CW/2 Transducer for use with:
ACUSON P500™ Ultrasound System

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

Clinical Application	Specific (Tracks:1& 3)	Mode of Operation				Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
		B	M	PWD	CWD				
Other (Track1 Only)									
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Note 1)								
	Neonatal Cephalic				P				
	Adult Cephalic				P				
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
Musculo-skel. (Superfic)									
Intra-vascular									
Other (Specify)									
Cardiac	Cardiac Adult				P				
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
Peripheral Vessel	Other (Specify)								
	Peripheral Vessel (Note 5)				P				
Vessel	Other (Specify)								

N = new indication; P = previously cleared K141846

Note 1	For example: breast, testes, thyroid, prostate, etc. Dynamic TCE Technology Advanced SteClear eSteImage For example: abdominal, vascular (upper and lower)	Note 6	Stress Echo eSteMeasure eSteScan AHP DTI Panoramic 2D Imaging (SteScape) Clarity VE Needle Visualization Intracardiac Echocardiography (ICE) Imaging CARTOSOUND Communication Probe Saver
Note 2		Note 7	
Note 3		Note 8	
Note 4		Note 9	
Note 5		Note 10	

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510(k) _____

Page 11 of 16

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: CW/5 Transducer for use with:
ACUSON P500™ Ultrasound System

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

Clinical Application	Mode of Operation						Other (Specify)		
	Other (Track1 Only)	Specific (Tracks 1& 3)	B	M	PWD	CWD		Color Doppler	Power Doppler
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Note 1)								
	Neonatal Cephalic				P				
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
	Cardiac Adult				P				
	Cardiac Pediatric								
	Intra-vascular (Cardiac)				P				
	Trans-esophageal (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
	Peripheral Vessel (Note 5)				P				
	Other (Specify)								

N = new indication; P = previously cleared by K141846

Note 1	For example: breast, testes, thyroid, prostate, etc.	Note 6	Stress Echo
Note 2	Dynamic TCE Technology	Note 7	eSieWearsure
Note 3	Advanced SieClear	Note 8	eSieScan
Note 4	eSieImage	Note 9	AHP
Note 5	For example: abdominal, vascular (upper and lower)	Note 10	DTI
		Note 11	Panoramic 2D Imaging (SieScape)
		Note 12	Clarity VE
		Note 13	Needle Visualization
		Note 14	Intracardiac Echocardiography (ICE) Imaging
		Note 15	CARTOSOUND Communication
		Note 16	Probe Saver

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

AcuNav 8F Transducer for use with:
ACUSON P500™ Diagnostic Ultrasound System

Intended Use:

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

Clinical Application	Specific (Tracks:1& 3)	Mode of Operation				Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
		B	M	PWD	CWD				
Other (Track1 Only)									
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Note 1)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac	P	P	P	P	P	P	BMDC	Note 2, 4, 10, 12, 14, 16
	Other (Specify)								
Peripheral Vessel	Peripheral Vessel (Note 5)								
	Other (Specify)								

N = new indication; P = previously cleared K141846

Note 1	For example: breast, testes, thyroid, prostate, etc. Dynamic TCE Technology Advanced SteClear eSteImage For example: abdominal, vascular (upper and lower)	Note 6	Stress Echo eSteMeasure eSteScan AHP DTI Panoramic 2D Imaging (SteScape) Needle Visualization Intracardiac Echocardiography (ICE) Imaging CARTOSOUND Communication Probe Saver
Note 2		Note 7	
Note 3		Note 8	
Note 4		Note 9	
Note 5		Note 10	

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **AcuNav 10F Transducer for use with:
 ACUSON P500™ Diagnostic Ultrasound System**
 Intended Use: **Diagnostic imaging or fluid flow analysis of the human body as follows:**

Clinical Application	Mode of Operation						Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
	B	M	PWD	CWD						
Other (Track1 Only)	Specific (Tracks:1& 3)									
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ (Note 1)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
Musculo-skel. (Convent.)										
Musculo-skel. (Superfic)										
Intra-vascular										
Other (Specify)										
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intra-vascular (Cardiac)									
	Trans-esophageal (Cardiac)									
	Intra-cardiac	P	P	P	P	P	P	BMDC	Note 2, 4, 10, 12, 14, 16	
	Other (Specify)									
Peripheral Vessel	Peripheral Vessel (Note 5)									
	Other (Specify)									

N = new indication; P = previously cleared K141846

Note 1	For example: breast, testes, thyroid, prostate, etc.	Note 6	Stress Echo
Note 2	Dynamic TCE Technology	Note 7	eSieWasure
Note 3	Advanced SieClear	Note 8	eSieScan
Note 4	eSieImage	Note 9	AHP
Note 5	For example: abdominal, vascular (upper and lower)	Note 10	DTI
		Note 11	Panoramic 2D Imaging (SieScape)
		Note 12	Clarity VE
		Note 13	Needle Visualization
		Note 14	Intracardiac Echocardiography (ICE) Imaging
		Note 15	CARTOSOUND Communication
		Note 16	Probe Saver

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: Soundstar 10F Transducer for use with:
ACUSON P500™ Diagnostic Ultrasound System
 Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Specific (Tracks:1& 3)	Mode of Operation				Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
		B	M	PWD	CWD				
Other (Track1 Only)									
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Note 1)								
Fetal Imaging & Other	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac	P	P	P	P	P	P	BMDC	Note 2, 4, 10, 12, 14, 15, 16
	Other (Specify)								
Peripheral Vessel	Peripheral Vessel (Note 5)								
	Other (Specify)								

N = new indication; P = previously cleared K141846

Note 1	For example: breast, testes, thyroid, prostate, etc.	Note 6	Stress Echo
Note 2	Dynamic TCE Technology	Note 7	eSieWearsure
Note 3	Advanced SieClear	Note 8	eSieScan
Note 4	eSieImage	Note 9	AHP
Note 5	For example: abdominal, vascular (upper and lower)	Note 10	DTI
		Note 11	Panoramic 2D Imaging (SieScape)
		Note 12	Clarity VE
		Note 13	Needle Visualization
		Note 14	Intracardiac Echocardiography (ICE) Imaging
		Note 15	CARTOSOUND Communication
		Note 16	Probe Saver

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: Soundstar eco 8F Transducer for use with:
ACUSON P500™ Diagnostic Ultrasound System
 Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Specific (Tracks:1& 3)	Mode of Operation					Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
		B	M	PWD	CWD					
Other (Track1 Only)										
Ophthalmic	Ophthalmic									
	Fetal									
	Abdominal									
	Intra-operative									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ (Note 1)									
Fetal Imaging & Other	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skel. (Convent.)									
	Musculo-skel. (Superfic)									
	Intra-vascular									
	Other (Specify)									
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intra-vascular (Cardiac)									
	Trans-esophageal (Cardiac)									
	Intra-cardiac	P	P	P	P	P	P	BMDC	Note 2, 4, 10, 12, 14, 15, 16	
	Other (Specify)									
Peripheral Vessel	Peripheral Vessel (Note 5)									
	Other (Specify)									

N = new indication; P = previously cleared K141846

Note 1	For example: breast, testes, thyroid, prostate, etc. Dynamic TCE Technology Advanced SteClear eSteImage For example: abdominal, vascular (upper and lower)	Note 6	Stress Echo eSteMeasure eSteScan AHP DTI Panoramic 2D Imaging (SteScape) Needle Visualization Intracardiac Echocardiography (ICE) Imaging CARTOSOUND Communication Probe Saver
Note 2		Note 7	
Note 3		Note 8	
Note 4		Note 9	
Note 5		Note 10	

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

Soundstar eco 10F Transducer for use with:
ACUSON P500™ Diagnostic Ultrasound System

Intended Use:

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

Clinical Application	Specific (Tracks:1& 3)	Mode of Operation				Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
		B	M	PWD	CWD				
Other (Track1 Only)									
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Note 1)								
Fetal Imaging & Other	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skel. (Convent.)								
	Musculo-skel. (Superfic)								
	Intra-vascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intra-vascular (Cardiac)								
	Trans-esophageal (Cardiac)								
	Intra-cardiac	P	P	P	P	P	P	BMDC	Note 2, 4, 10, 12, 14, 15, 16
	Other (Specify)								
Peripheral Vessel	Peripheral Vessel (Note 5)								
	Other (Specify)								

N = new indication; P = previously cleared K141846

Note 1	For example: breast, testes, thyroid, prostate, etc.	Note 6	Stress Echo
Note 2	Dynamic TCE Technology	Note 7	eStelMeasure
Note 3	Advanced SteClear	Note 8	eStelScan
Note 4	eStelImage	Note 9	AHP
Note 5	For example: abdominal, vascular (upper and lower)	Note 10	DTI
		Note 11	Panoramic 2D Imaging (StelScape)
		Note 12	Clarity VE
		Note 13	Needle Visualization
		Note 14	Intracardiac Echocardiography (ICE) Imaging
		Note 15	CARTOSOUND Communication
		Note 16	Probe Saver

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510(k) Summary
Prepared October 24, 2016

Sponsor: 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: Shelly Pearce
Telephone: (650) 279-0134
Fax: (650) 694-5580

Device Name: ACUSON P500™ Ultrasound System

Common Name: Diagnostic Ultrasound System with Accessories

Classification:

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

Device	21 CFR section	Product Code
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
Diagnostic Intravascular Catheter	870.1200	90-OBJ

A. Legally Marketed Predicate Devices

The ACUSON P500™ Ultrasound System is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to our current product, the

ACUSON P500 (K150050), ACUSON X700 (K141846), ACUSON SC2000 (K162221), ACUSON NX2 (K161787), ACUSON Freestyle (K162417) and Vivid i&q (K121062)

B. Device Description:

The ACUSON P500™ Ultrasound System is a multi-purpose mobile, software controlled, diagnostic ultrasound system 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, Tissue Doppler Image, Power (Amplitude) Doppler Mode and a combination of modes on a Flat Panel Display.

C. Intended Use

The ACUSON P500 ultrasound imaging system is intended for the following applications: Fetal, Abdominal (including liver), Pediatric, Small Parts, Transcranial, OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures), Pelvic, Neonatal, Cardiac, IntraCardiac, Vascular (including Peripheral Vessel), Musculoskeletal, Superficial Musculoskeletal, and Urology applications.

The system also provides the ability to measure anatomical structures fetal, abdominal, small organ, transrectal, transvaginal, cardiovascular, peripheral vessel, musculoskeletal (conventional), and 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.

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 Imaging."

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

D. Substantial Equivalence

The ACUSON P500™ Ultrasound System is substantially equivalent to the ACUSON P500 (K150050), ACUSON X700 (K141846), ACUSON SC2000 (K162221), ACUSON NX2 (K161787), ACUSON Freestyle (K162417) and vivid i/q (K121062). All systems transmit

ultrasonic energy into patients, 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.

Feature / Characteristic	Predicate Device Vivid i/q (K121062)	Predicate Device ACUSON Freestyle (K162417)	Predicate Device ACUSON X700 (K141846)	Predicate Device ACUSON SC2000 (K162221)	Predicate Device ACUSON NX2 (K161787)	Predicate Device ACUSON P500 (K150050)	Submission Device ACUSON P500
Indications for Use:							
▪ Fetal	-	√	√	-	√	√	√
▪ Abdominal	-	√	√	√	√	√	√
▪ Small Organ	-	√	√	√	√	√	√
▪ Cardiac	-	√	√	√	√	√	√
▪ Transrectal	-	-	√	√	√	√	√
▪ Transvaginal	-	-	√	-	√	√	√
▪ Peripheral vessel	-	√	√	√	√	√	√
▪ Musculo-skeletal (conventional)	-	√	√	√	√	√	√
▪ Musculo-skeletal (superficial)	-	√	√	√	√	√	√
▪ Emergency Medicine	-	√	√	√	√	√	√
▪ Intracardiac	-	-	√	√	-	-	√
Modes:							
▪ B	-	√	√	√	√	√	√
▪ M	-	√	√	√	√	√	√
▪ PWD (Pulsed Wave Doppler)	-	√	√	√	√	√	√
▪ CWD (Continuous Wave Doppler)		√	√	√	√	√	√
▪ D (Color Doppler)	-	√	√	√	√	√	√
▪ Power Doppler (Amplitude Doppler)	-	√	√	√	√	√	√
▪ Combined (BM, BC, BCM, BCD)	-	√	√	√	√	√	√
▪ THI (Tissue Harmonic Imaging)	-	-	√	√	√	√	√
▪ M-THI	-	-	√	√	√	√	√

Features:							
▪ 3D Imaging (3-Scape)	-	-	√	-	√	-	-
▪ 3D Measurements	-	-	√	√	√	-	-
▪ 4D Basic Imaging (fourSight 4D)	-	-	√	-	√	-	-
▪ Panoramic 2D Imaging (SieScape)	-	-	√	-	√	-	√
▪ Cardiac Imaging physiological signal display multiplane TEE fourSight TEE Imaging	-	-	√	√	-	-	-
▪ Dual-Beam Processing	-	-	√	√	√	√	√
▪ Quad-Beam Processing	-	-	√	√	√	√	√
▪ SynAps	-	-	√	-	√	-	-
▪ Clip Capture	-	√	√	√	√	√	√
▪ Tissue Grayscale Optimization (TGO)	-	-	√	-	√	-	-
▪ Spectral DTI	-	-	√	√	√	-	√
▪ Syngo Auto OB	-	-	√	-	√	-	-
▪ Stress Echo	-	-	√	√	√	-	√
▪ 2D(color) DTI	-	-	√	√	√	-	√
▪ DIMAQ (PIMS Workplace)	-	-	√	-	√	√	√
▪ Vascular Enhancement (Clarify VE)	-	-	√	√	√	-	√
▪ eSieImage	-	-	-	-	-	√	√
▪ Advance SieClear	-	-	√	√	√	√	√
▪ Multiple Frequency Imaging(MultiHertz)	-	√	√	√	√	√	√
▪ Digital Architecture	-	√	√	√	√	√	√
▪ DICOM SR Vascular	-	-	√	√	√	√	√
▪ DICOM SR OB/GYN	-	-	√	√	√	√	√
▪ DICOM SR Cardiac	-	-	√	√	√	-	√
▪ Dynamic TCE	-	-	√	√	√	√	√
▪ Syngo AHP	-	-	√	√	√	-	√
▪ eSieMeasure	-	-	-	√	-	-	√
▪ eSieScan	-	-	-	√	-	-	√

▪ Enhanced Needle Visualization	-	√	-	-	-	-	√
▪ Probe Saver	√	-	-	-	-	-	√
▪ Intracardiac Echocardiography (ICE) Imaging	-	-	√	√	-	-	√
▪ CARTOSOUND Communication	-	-	√	√	-	-	√
▪ Monitor: 15.4"WXGA (FPD)	-	√ (15" LED LCD)	√ (20" FPD)	√ (21.5" FPD)-	√ (21.5" FPD)	√ (15.4" FPD)	√
▪ Wireless	-	√	√	√	√	√	√
# Channels	-	64	128	192	64	64	64
Output Display Standard (Track 3)	-	√	√	√	√	√	√
Patient Contact Materials	-	Tested to ISO 10993-1	Tested to ISO 10993-1	Tested to ISO 10993-1	Tested to ISO 10993-1	Tested to ISO 10993-1	Tested to ISO 10993-1
ANSI/AAMI ES 60601-1 Certified	-	√ (UL60601-1)	√ (UL60601-1)	√ (UL60601-1)	√ (UL60601-1)	√ (UL60601-1)	√

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 has been found to conform with applicable medical device safety standards. The system complies 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
- IEC 60601-1-2
- IEC 60601-2-18
- IEC 60601-2-37
- ISO 10993-1

Cleared patient contact materials, electrical and mechanical safety are unchanged.

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

Since the ACUSON P500™ 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 with 21 CFR 820 Quality System Regulation and ISO 13485:2003 quality system standards. The product is designed to conform with applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of Siemens Medical Solutions USA, Inc that the ACUSON P500™ Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

The ACUSON P500™ Ultrasound System is verified and validated according to the company's design control process.