



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

September 9, 2014

Siemens Medical Solutions, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K142395
Trade/Device Name: SC2000/X300 Diagnostic 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: August 21, 2014
Received: August 27, 2014

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.

This determination of substantial equivalence applies to the following transducers intended for use with the SC2000/X300 Diagnostic Ultrasound System, as described in your premarket notification:

SC2000 Transducer Model Number		
AcuNav 8F	Soundstar eco 8F	9L4
6C1HD	V5M	4V1c
8V3	CW2	4Z1c
AcuNav 10F	ACUSON AcuNav™ V 10F	SoundStar 10F
V7M	10V4	

X300 Transducer Model Number		
AcuNav 8F	Soundstar eco 8F	P4-2
CH5-2	VF10-5	L9-5

EC9-4	EV9-4	VF13-5
P8-4	BE 9-4	CW2
CW5	AcuNav 10F	V5Ms
4V1c	VF13-5SP	C8-5
8L3	10V4	C7F2
EV9F4	L13F5	VF8-3
P5-1	C6-2	SoundStar 10F
P9-4		

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

Janine M. Morris
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): K142395

Device Name: ACUSON X300™ Diagnostic Ultrasound System
SONOVISTA X300 Diagnostic Ultrasound System
ACUSON X300™ Diagnostic Ultrasound System, premium edition

The Siemens Acuson X300 ultrasound imaging system is intended for the following applications: General Radiology, Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Neonatal/Adult Cephalic, Cardiac, Transesophageal, Pelvic, Transcranial, OB/GYN, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

The Acuson Acunav and Soundstar Ultrasound Catheter are 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)

X Prescription Use (21 CFG 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

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FOR FDA USE ONLY

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Neuro)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-rectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-vaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-urethral										
	Trans-esoph. (non-Card.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Convent.)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra -vascular		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
Cardiac	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-esophageal (Cardiac)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-Cardiac		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
Peripheral	Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
Vessel	Other (Specify)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11

N = new indication; P = previously cleared K080760, 121699

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

Note 3 3D imaging

Note 5 Power SieScape panoramic imaging

Note 7 Contrast agent imaging

Note 9 Tissue Equalization Technology

Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging

Note 4 B&W SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 8 SieClear multi-view spatial compounding

Note 10 Intracardiac imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

**AcuNav 8F Intracardiac Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

Intended Use:

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

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 6)								
	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	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Cardiac Pediatric	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Intra-vascular (Cardiac)	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Trans-esophageal (Cardiac)								
	Intra-cardiac	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axis Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging

Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSight 4D imaging
Note 20 Contrast Agent Imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **Soundstar eco 8F Intracardiac Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

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

Clinical Application		Mode of Operation							
Other (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Power Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Note 6)								
	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	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Other (Specify)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Cardiac Pediatric	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Intra-vascular (Cardiac)	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Trans-esophageal (Cardiac)								
	Intra-cardiac	P	P	P	P	P	P	BMDC	Note 2,8,9,13,14,16
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

N = new indication; P = previously cleared K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Dynamic TCE Technology
Note 3 SieClear
Note 4 Advanced SieClear
Note 5 3-Scape 3D Imaging
Note 6 For example: abdominal, vascular
Note 7 Stress Echo Imaging
Note 8 Axius Edge Assisted Ejection Fraction
Note 9 Clarify Vascular Enhancement Technology
Note 10 SieScape Panoramic Imaging

Note 11 syngo Arterial Health Package (AHP)
Note 12 syngo Auto OB Measurements
Note 13 syngo Auto Left Heart (Auto LH) Technology
Note 14 syngo Velocity Vector Imaging Technology
Note 15 CartoSound Communication
Note 16 Intracardiac Echocardiography (ICE) Imaging
Note 17 syngo fourSight TEE View
Note 18 syngo Mitral Valve Assessment (MVA)
Note 19 syngo fourSight 4D imaging
Note 20 Contrast Agent Imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Neuro)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-rectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-vaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-urethral										
	Trans-esoph. (non-Card.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Convent.)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra -vascular		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
Cardiac	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-esophageal (Cardiac)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-Cardiac		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
Peripheral	Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
Vessel	Other (Specify)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11

N = new indication; P = previously cleared by K080760, 121699

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

Note 3 3D imaging

Note 5 Power SieScape panoramic imaging

Note 7 Contrast agent imaging

Note 9 Tissue Equalization Technology

Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging

Note 4 B&W SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 8 SieClear multi-view spatial compounding

Note 10 Intracardiac imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence 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 Sector Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,5,6,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)										
	Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	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		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 3 3D imaging
 Note 5 Power SieScape panoramic imaging
 Note 7 Contrast agent imaging
 Note 9 Tissue Equalization Technology
 Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
 Note 4 B&W SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 8 SieClear multi-view spatial compounding
 Note 10 Intracardiac imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

CH5-2 Convex Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	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 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 3 3D imaging
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 Note 10 Intracardiac imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

VF10-5 Linear Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1I & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 3 3D imaging
 Note 5 Power SieScape panoramic imaging
 Note 7 Contrast agent imaging
 Note 9 Tissue Equalization Technology
 Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
 Note 4 B&W SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 8 SieClear multi-view spatial compounding
 Note 10 Intracardiac imaging

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

**L9-5 Linear Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

Intended Use:

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-Cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
Note 5 Power SieScape panoramic imaging
Note 7 Contrast agent imaging
Note 9 Tissue Equalization Technology
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding
Note 10 Intracardiac imaging

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

EC9-4 Convex Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1I & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal										
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-vaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	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										
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 3 3D imaging
 Note 5 Power SieScape panoramic imaging
 Note 7 Contrast agent imaging
 Note 9 Tissue Equalization Technology
 Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
 Note 4 B&W SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 8 SieClear multi-view spatial compounding
 Note 10 Intracardiac imaging

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

EV9-4 Convex Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal										
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-vaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	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										
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 3 3D imaging
 Note 5 Power SieScape panoramic imaging
 Note 7 Contrast agent imaging
 Note 9 Tissue Equalization Technology
 Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
 Note 4 B&W SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 8 SieClear multi-view spatial compounding
 Note 10 Intracardiac imaging

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **VF13-5 Linear Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
Note 5 Power SieScape panoramic imaging
Note 7 Contrast agent imaging
Note 9 Tissue Equalization Technology
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding
Note 10 Intracardiac imaging

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **P8-4 Phased Sector Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,5,6,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)										
	Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
Note 5 Power SieScape panoramic imaging
Note 7 Contrast agent imaging
Note 9 Tissue Equalization Technology
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding
Note 10 Intracardiac imaging

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

BE 9-4 Convex Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 11 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Abdominal										
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Adult Cephalic										
	Trans-rectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Trans-vaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	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										
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 3 3D imaging
 Note 5 Power SieScape panoramic imaging
 Note 7 Contrast agent imaging
 Note 9 Tissue Equalization Technology
 Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
 Note 4 B&W SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 8 SieClear multi-view spatial compounding
 Note 10 Intracardiac imaging

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **CW2 Continuous Wave Doppler Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

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

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal					P					
	Abdominal					P					
	Intra-operative (Note 6)					P					
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric					P					
	SmallOrgan (Note 1)					P					
	Neonatal Cephalic					P					
	Adult Cephalic					P					
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)					P					
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult					P					
	Cardiac Pediatric					P					
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral	Peripheral vessel					P					
Vessel	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 3 3D imaging
 Note 5 Power SieScape panoramic imaging
 Note 7 Contrast agent imaging
 Note 9 Tissue Equalization Technology
 Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
 Note 4 B&W SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 8 SieClear multi-view spatial compounding
 Note 10 Intracardiac imaging

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

CW5 Continuous Wave Doppler Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

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

Clinical Application		Mode of Operation									
Other (Track1 Only)	Specific (Tracks1l& 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal					P					
	Abdominal					P					
	Intra-operative (Note 6)					P					
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric					P					
	SmallOrgan (Note 1)					P					
	Neonatal Cephalic					P					
	Adult Cephalic					P					
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)					P					
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult					P					
	Cardiac Pediatric					P					
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-Cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel					P					
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 3 3D imaging
 Note 5 Power SieScape panoramic imaging
 Note 7 Contrast agent imaging
 Note 9 Tissue Equalization Technology
 Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
 Note 4 B&W SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 8 SieClear multi-view spatial compounding
 Note 10 Intracardiac imaging

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

AcuNav 10F Intracardiac Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems

Intended Use:

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 11 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal										
	Abdominal										
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	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		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Intra-vascular (Cardiac)		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Trans-esophageal (Cardiac)										
	Intra-cardiac		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Other (Specify)										
Peripheral Vessel	Peripheral vessel										
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 3 3D imaging
 Note 5 Power SieScape panoramic imaging
 Note 7 Contrast agent imaging
 Note 9 Tissue Equalization Technology
 Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
 Note 4 B&W SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 8 SieClear multi-view spatial compounding
 Note 10 Intracardiac imaging

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **V5Ms TEE Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal										
	Abdominal										
	Intra-operative (Note 6)										
	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		BMDC	Note 2,3,7,8,9,11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,11
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,11
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel										
	Other (Specify)										

N = new indication; P = previously cleared by K090276

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
Note 5 Power SieScape panoramic imaging
Note 7 Contrast agent imaging
Note 9 Tissue Equalization Technology
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding
Note 10 Intracardiac imaging

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **4V1c Phased Sector Array Transducer for use with:**
ACUSON X300 Diagnostic Ultrasound Systems
 Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,5,6,7,8,9
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Small Organ (Note 1)										
	Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	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		BMDC	Note 2,3,4,5,7,8,9
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 3 3D imaging
 Note 5 Power SieScape panoramic imaging
 Note 7 Contrast agent imaging
 Note 8 SieClear multi-view spatial compounding
 Note 9 Tissue Equalization Technology
 Note 10 Intracardiac imaging
 Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
 Note 4 B&W SieScape panoramic imaging
 Note 6 For example: abdominal, vascular

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **VF13-5SP Linear Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**
Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal										
	Abdominal										
	Intra-operative (Note 6)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Neuro)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
Note 5 Power SieScape panoramic imaging
Note 7 Contrast agent imaging
Note 9 Tissue Equalization Technology
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding
Note 10 Intracardiac imaging

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **C8-5 Tightly Curved Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Adult Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Musculo-skel. (Superfic)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Cardiac Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
Note 5 Power SieScape panoramic imaging
Note 7 Contrast agent imaging
Note 9 Tissue Equalization Technology
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding
Note 10 Intracardiac imaging

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

510(k)_____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **8L3 Linear "Regel" Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Musculo-skel. (Superfic)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

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

Note 3 3D imaging

Note 5 Power SieScape panoramic imaging

Note 7 Contrast agent imaging

Note 9 Tissue Equalization Technology

Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging

Note 4 B&W SieScape panoramic imaging

Note 6 For example: abdominal, vascular

Note 8 SieClear multi-view spatial compounding

Note 10 Intracardiac imaging

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **10V4 Phased Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Small Organ (Note 1)										
	Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
Note 5 Power SieScape panoramic imaging
Note 7 Contrast agent imaging
Note 9 Tissue Equalization Technology
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding
Note 10 Intracardiac imaging

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **C7F2 Curved Array Mechanical 3D/4D Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	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 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
Note 5 Power SieScape panoramic imaging
Note 7 Contrast agent imaging
Note 9 Tissue Equalization Technology
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding
Note 10 Intracardiac imaging

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **EV9F4 Curved Array Mechanical 3D/4D Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal										
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-vaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	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										
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
Note 5 Power SieScape panoramic imaging
Note 7 Contrast agent imaging
Note 9 Tissue Equalization Technology
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding
Note 10 Intracardiac imaging

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **L13F5 3D/4D Mechanical Wobbler Linear Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Musculo-skel. (Superfic)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
Note 5 Power SieScape panoramic imaging
Note 7 Contrast agent imaging
Note 9 Tissue Equalization Technology
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding
Note 10 Intracardiac imaging

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **VF8-3 Linear Array Transducer for use with:**
ACUSON X300 Diagnostic Ultrasound Systems
 Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skel. (Convent.)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 Note 3 3D imaging
 Note 5 Power SieScape panoramic imaging
 Note 7 Contrast agent imaging
 Note 9 Tissue Equalization Technology
 Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
 Note 4 B&W SieScape panoramic imaging
 Note 6 For example: abdominal, vascular
 Note 8 SieClear multi-view spatial compounding
 Note 10 Intracardiac imaging

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **P5-1 Phased Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)										
	Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	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		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
Note 5 Power SieScape panoramic imaging
Note 7 Contrast agent imaging
Note 9 Tissue Equalization Technology
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding
Note 10 Intracardiac imaging

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **C6-2 Convex Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	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 2,3,4,5,7,8,9,11
	Musculo-skel. (Superfic)										
	Intra-vascular										
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
Note 5 Power SieScape panoramic imaging
Note 7 Contrast agent imaging
Note 9 Tissue Equalization Technology
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding
Note 10 Intracardiac imaging

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **SoundStar 10F Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal										
	Abdominal										
	Intra-operative (Note 6)										
	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		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Other (Specify)										
Cardiac	Cardiac Adult		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Intra-vascular (Cardiac)		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Trans-esophageal (Cardiac)										
	Intra-cardiac		P	P	P	P	P	P		BMDC	Note 2,3,7,8,9,10,11
	Other (Specify)										
Peripheral Vessel	Peripheral vessel										
	Other (Specify)										

N = new indication; P = previously cleared by K080760, 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
Note 5 Power SieScape panoramic imaging
Note 7 Contrast agent imaging
Note 9 Tissue Equalization Technology
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding
Note 10 Intracardiac imaging

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **P9-4 Phased Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**

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

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 1 & 3)	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,5,6,7,8,9,11
	Intra-operative (Note 6)										
	Intra-operative (Neuro)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Laparoscopic										
	Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Small Organ (Note 1)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	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		BMDC	Note 2,3,4,5,7,8,9,11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Cardiac Neonatal)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
Peripheral Vessel	Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11
	Other (Specify)										

N = new indication; P = previously cleared by FDA 121699

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 3 3D imaging
Note 5 Power SieScape panoramic imaging
Note 7 Contrast agent imaging
Note 9 Tissue Equalization Technology
Note 11 Dynamic TCE

Note 2 Ensemble tissue harmonic imaging
Note 4 B&W SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 8 SieClear multi-view spatial compounding
Note 10 Intracardiac imaging

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

510(k) _____

Indications for Use

510(k) Number (if known):

Device Name: ACUSON SC2000 Diagnostic Ultrasound System

The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transesophageal, Adult Cephalic, Peripheral Vessel, Abdominal, Abdominal Intraoperative, Intraoperative, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications. The system also provides the ability to measure anatomical structures 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 typical examinations performed using the SC2000 Ultrasound System are:

Cardiac Imaging Applications and Analysis

The system transmits ultrasound energy into adult, pediatric, neonatal, and fetal cardiac patients creating 2D (B), 3D, M-Mode (M), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave (PW) Doppler, and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the heart, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system also supports catheters which are intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients.

The system transmits ultrasound energy from either a transthoracic or transesophageal approach in adult and pediatric patients; and from a transthoracic approach in neonatal and fetal cardiac patients creating 2D (B), 3D, M-Mode (M), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave (PW) Doppler, and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the heart, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system has Cardiac Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Vascular Imaging Applications and Analysis

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the carotid arteries or jugular veins in the neck; superficial and deep veins and arteries in the arms, legs and abdomen; and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system has Vascular Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Superficial Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of conventional or superficial musculoskeletal structures and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

Intraoperative Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), and Pulsed Wave Doppler (PWD) to obtain images and blood flow velocity that provide guidance during intraoperative procedures.

Transcranial Imaging Applications

The system transmits ultrasound energy into the cranium of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the brain and surrounding anatomical structures to evaluate the presence or absence of pathology.

The system provides Measurement Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

The Acuson Acunav and Soundstar Ultrasound Catheter are 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 (21 CFG 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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FOR FDA USE ONLY

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

510(k) Number (if known):

Device Name: **SC2000 Diagnostic Ultrasound System**

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

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: 3D	Other: Real Time 3D
Ophthalmic												
Fetal		P	P	P	P	P	P		P*	P		P
Abdominal		P	P	P	P	P	P		P*	P		
Intraoperative Abdominal		P	P	P	P	P	P		P*	P		
Intraoperative Neurological												
Pediatric		P	P	P	P	P	P		P*	P	P	P
Small Organ (specify)												
Neonatal Cephalic												
Adult Cephalic		P	P	P	P	P	P		P*	P		
Cardiac		P	P	P	P	P	P		P*	P	P	P
Trans-esophageal		P	P	P	P	P			P*		P	
Transrectal												
Transvaginal												
Transurethral												
Intra-Luminal		P	P	P	P	P	P		P*			P
Peripheral Vessel		P	P	P	P	P	P	P	P*	P		
Laparoscopic												
Musculo-skeletal Conventional		P	P	P		P	P	P	P*	P		
Musculo-skeletal Superficial		P	P	P		P	P	P	P*	P		
Other (Neonatal Cardiac)		P	P	P	P	P	P		P*	P		
Other (Intra-Cardiac)		P		P	P	P	P		P*			P

N=new indication. P = Previously Cleared K072365, K102017, K113179, K132654

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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

510(k) Number (if known):

Device Name: **AcuNav 8F** Intracardiac Transducer for use with:

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

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P*		
Small Organ (specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*		
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal		P	P	P	P	P	P		P*		
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (Intra-Cardiac)		P	P	P	P	P	P		P*		

N=new indication. P = Previously Cleared K072365, K102017, K113179, K132654

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler

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

510(k) Number (if known):

Device Name:

Soundstar eco 8F Intracardiac Transducer for use with:
ACUSON SC2000 Diagnostic Ultrasound Systems

Intended Use:

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

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P*		
Small Organ (specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*		
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal		P	P	P	P	P	P		P*		
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (Intra-Cardiac)		P	P	P	P	P	P		P*		

N=new indication. P = Previously Cleared

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler

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

510(k) _____

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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **9L4**

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

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal										
Peripheral Vessel		P	P	P		P	P	P	P*	P
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P	P	P*	P
Musculo-skeletal Superficial		P	P	P		P	P	P	P*	P
Other (specify)										

N=new indication. P = Previously Cleared in 510(k) K072365, K102017, K113179, K132654

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **6C1HD**

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

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative										
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)		P	P	P	P	P	P		P*	P
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Abdominal Vascular)		P	P	P	P	P	P		P*	P

N=new indication. P = Previously Cleared in 510(k) K072365, K102017, K132654

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **V5M**

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

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P			P*		P
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P			P*		P
Trans-esophageal		P	P	P	P	P			P*		P
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N=new indication. P = Previously Cleared in 510(k) K072365, K102017, K113179, K132654

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **4V1c**

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

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P *	P
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P *	P
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic		P	P	P	P	P	P		P *	P
Cardiac		P	P	P	P	P	P		P *	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Neonatal Cardiac)		P	P	P	P	P	P		P *	P

N=new indication. Previously Cleared in 510(k) K072365, K102017, K113179, K132654

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **8V3**

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

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P *	P
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P *	P
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P *	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Neonatal Cardiac)		P	P	P	P	P	P		P *	P

N=new indication. Previously Cleared in 510(k) K102017, K113179, K132654

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **CW2**

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

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric					P					
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					P					
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal										
Peripheral Vessel					P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N=new indication. Previously Cleared in 510(k) K072365, K102017, K113179, K132654

Additional Comments:

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510(k)_____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **4Z1c**

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

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal		P	P	P	P	P			P*	P	P
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P			P*	P	P
Small Organ (specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P			P*	P	P
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N=new indication. P = Previously Cleared in 510(k) K072365, K102017, K113179, K132654

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

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

Intended Use: Catheter is intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P*		
Small Organ (specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*		
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal		P	P	P	P	P	P		P*		
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (Intra-Cardiac)		P	P	P	P	P	P		P*		

N=new indication. P = Previously Cleared in 510(k) K071234, K093812, K113179, K132654

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler

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

510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

ACUSON AcuNav™ V 10F Ultrasound Catheter

Intended Use:

Catheter is intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P*		P
Small Organ (specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*		P
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal		P	P	P	P	P	P		P*		P
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (Intra-Cardiac)		P	P	P	P	P	P		P*		P

N=new indication. P = Previously Cleared in 510(k) K081808, K113179, K132654

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

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

Intended Use: Catheter is intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ (specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*		
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal		P	P	P	P	P	P		P*		
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (Intra-Cardiac)		P	P	P	P	P	P		P*		

N=new indication. P = Previously Cleared in 510(k) K070242, K113179, K132654

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **V7M**

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

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: 3D
Ophthalmic											
Fetal											
Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P			P*		P
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P			P*		P
Trans-esophageal		P	P	P	P	P			P*		P
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N=new indication. P = Previously Cleared in 510(k) K111674, K132654

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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510(k) _____

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **10V4**

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

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P *	P
Abdominal		P	P	P	P	P	P		P *	P
Intraoperative Abdominal		P	P	P	P	P	P		P *	P
Intraoperative Neurological		P	P	P	P	P	P		P *	P
Pediatric		P	P	P	P	P	P		P *	P
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P *	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Neonatal Cardiac)		P	P	P	P	P	P		P *	P

N=new indication. Previously Cleared in 510(k) K111674, K132654

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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

510(k) _____

510(k) Summary
Prepared August 19, 2014

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

Contact Person: Shelly Pearce
Telephone: (650) 694-5988

Submission Date: August 7, 2014

Device Name: SC2000, X300 Diagnostic Ultrasound Systems

Common Name: Diagnostic Ultrasound System with Accessories

Classification:

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

Ultrasonic Pulsed Doppler Imaging System	CFR # 892.1550	Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System	CFR # 892.1560	Product Code 90-IYO
Diagnostic Intravascular Catheter	CFR # 870.1200	Product Code OBJ

A. Legally Marketed Predicate Devices

The device modifications described in this 510(k) are substantially equivalent to the company's own devices, previously cleared on K132654 (SC2000), K121699 (X300), K123001 (X700), K141846 (X700). The catheter is substantially equivalent to K140318 (SSe8F), K071234 (AN8F).

B. Device Description:

The Diagnostic Ultrasound Systems are multi-purpose mobile, software controlled diagnostic ultrasound systems with on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of modes, 3D Imaging, or Harmonic Imaging and 4D imaging.

C. Intended Use

SC2000 -

The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neonatal and Fetal Cardiac, Pediatric, Transesophageal, Adult Cephalic, Peripheral Vessel, Abdominal, Intraoperative Abdominal, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications. The system also provides the ability to measure anatomical structures 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 typical examinations performed using the SC2000 Ultrasound System are:

Cardiac Imaging Applications and Analysis

The system transmits ultrasound energy into adult, pediatric, neonatal, and fetal cardiac patients creating 2D (B), 3D, M-Mode (M), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave (PW) Doppler, and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the heart, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images. The system also supports catheters which are intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients. The system has Cardiac Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Vascular Imaging Applications and Analysis

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the carotid arteries or jugular veins in the neck; superficial and deep veins and arteries in the arms and legs and abdomen; and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images. The system has Vascular Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Superficial Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of conventional or superficial musculoskeletal structures and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

Intraoperative Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), and Pulsed Wave Doppler (PWD) to obtain images and blood flow velocity that provide guidance during intraoperative procedures.

Transcranial Imaging Applications

The system transmits ultrasound energy into the cranium of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous

Wave Doppler (CWD) to obtain images and blood flow velocity of the brain and surrounding anatomical structures to evaluate the presence or absence of pathology. The system provides Measurement Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

The Acuson Acunav and Soundstar Ultrasound Catheter are 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.

X300:

The Siemens Acuson X300 ultrasound imaging system is intended for the following applications: General Radiology, Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Neonatal/Adult Cephalic, Cardiac, Transesophageal, Pelvic, Transcranial, OB/GYN, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the “ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging”.

The Acuson Acunav and Soundstar Ultrasound Catheter are 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 device modifications described in this 510(k) are substantially equivalent to the company's own devices, previously cleared on K132654 (SC2000), K121699 (X300), K123001 (X700), K141846 (X700). The catheter is substantially equivalent to K140318 (SSe8F), K071234 (AN8F). The submission devices are substantially equivalent to the predicate devices with regard to both intended use and technological characteristics.

Description	This submission (All Devices)	Acuson X700 K141846	Acuson SC2000™ K132654	Acuson X300 - K121699 / X700 – K123001
System:				
Hardware Safety – EN60601-1 Certified	X	X	X	X
Acoustic Thermal Safety – EN60601-2-37 Certified	X	X	X	X

Medical device software – Software Life Cycle Process - IEC 62304	X	X	X	X
Transducers:				
As cleared in the device's previous 510(k)	X	X	X	X
AcuNav 8F Catheter	X	X	X	X
Soundstar eco 8F Catheter	X	X		
Software Features				
As cleared in the device's previous 510(k)	X	X	X	X

E. A brief discussion of nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence

The devices have 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 systems comply with the following voluntary standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, 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
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
- EN/IEC 60601-1
- EN/IEC 60601-1-1
- EN/IEC 60601-1-2
- EN/IEC 62304
- EN/IEC 62366
- EN/IEC 60601-2-18
- EN/IEC 60601-2-25
- ISO 10993-1 Biocompatibility

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 modified devices use 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 that the modified devices are substantially equivalent with respect to safety and effectiveness to devices currently cleared for market. The modified devices are verified and validated according to the company's design control process.