

K093531

510(k) Summary

Sponsor: Siemens Medical Solutions, Inc., DEC - 1, 2009
Ultrasound Division
1230 Shorebird Way
Mountain View, California 94043

Contact Person: Shelly Pearce
Telephone: (650) 694-5988
Fax: (650) 694-5580

Submission Date: October 06, 2009

Device Name: ACUSON X300™ Diagnostic Ultrasound System

Common Name: Diagnostic Ultrasound System with Accessories

Classification:

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

Ultrasonic Pulsed Doppler Imaging System	FR # 892.1550	Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System	FR # 892.1560	Product Code 90-IYO
Diagnostic Ultrasound Transducer	FR # 892.1570	Product Code 90-ITX
Diagnostic Intravascular Catheter	FR # 870.1200	Product Code 74-DQO

A. Legally Marketed Predicate Devices

The Siemens Acuson X300 ultrasound system is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to our current product, the Siemens Acuson X300 ultrasound system (K090276, K072676, K071036 and K061946) and the following:

- K061980, Siemens Acuson X500™ Ultrasound System
- K081121, ACUSON X150 Ultrasound System
- K090276, ACUSON X300™ Diagnostic Ultrasound System, Premium Edition

B. Device Description:

The Acuson X300 has been designed to meet the following product safety 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 60601-1-4
- EN/IEC 60601-1-6
- EN/IEC 60601-2-18
- EN/IEC 60601-2-25
- IEC 1157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

C. Intended Use

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.

D. Substantial Equivalence

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

E. Performance Data

The Acuson X300 modifications are verified and validated according to the company's design control process.



DEC - 1 2009

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

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

Re: K093531

Trade/Device Name: ACUSON X300™ Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX, and DQO
Dated: November 13, 2009
Received: November 16, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

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

Transducer Model Number

P4-2 Phased Sector Array

CH5-2 Convex Array

VF10-5 Linear Array

L9-5 Linear Array

EC9-4 Convex Array

EV9-4 Convex Array
VF13-5 Linear Array
P8-4 Phased Sector Array
BE9-4 Convex Array
CW2 Continuous Wave Doppler
CW5-Continuous Wave Doppler
AcuNav 8F Intracardiac
AcuNav 10F Intracardiac
V5Ms TEE
4V1c Phased Sector Array
VF13-5SP Linear Array
C8-5 Tightly Curved Array
8L3 Linear “Regel”
10V4 Phased Array
C7F2 Curved Array Mechanical 3D/4D
EV9F4 Curved Array Mechanical 3D/4D
L13F5 3D/4D Mechanical Wobbler Linear
VF8-3 Linear Array
P5-1 Phased Array
C6-2 Convex Array
SoundStar 10F
P9-4 Phased Array
P4-2 Litho Phased Sector Array
BP9-4 Convex Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. Also, please

note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,



En Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use Statement

510(k) Number (if known): K093531

Device Name: ACUSON X300™ Diagnostic Ultrasound System

Indications For Use:

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.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093531

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		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. (Superficial)		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 2,3,4,5,7,8,9,11,12
	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 Vessel	Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,9,11,12
	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 K090276

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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 12 AHP

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

[Signature]
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093531

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. (Superficial)											
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 K090276
- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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

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Prescription Use (Per 21 CFR 801.109)

[Signature]

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

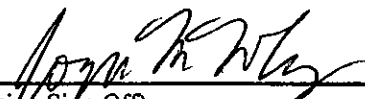
Device Name: **CH5-2 Convex Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**
Intended Use: **Diagnostic imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 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 2,3,4,5,7,8,9,11
	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. (Superficial)											
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 K090276

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093531

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 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. (Superficial)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
Intra-vascular											
Other (Specify)											
Cardiac	Cardiac Adult										
	Cardiac Pediatric										Note 12
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
Other (Specify)											
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11,12
	Other (Specify)										

- N = new indication; P = previously cleared by K090276
- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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 12 AHP

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Prescription Use (Per 21 CFR 801.109)

[Signature]

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093531

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 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 2,3,4,5,7,8,9,11
	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. (Superficial)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
Intra-vascular											
Other (Specify)											
Cardiac	Cardiac Adult										
	Cardiac Pediatric										Note 12
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-Cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11,12
	Other (Specify)										

N = new indication; P = previously cleared by K090276

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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 12 AHP

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093531

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 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 K090276

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
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- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093531

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 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 2,3,4,5,7,8,9,11
	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. (Superficial)											
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 K090276

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic Imaging
- Note 6 For example: abdominal, vascular
- 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

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093531

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 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 2,3,4,5,7,8,9,11
	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
Musculo-skel. (Superficial)			P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
Intra-vascular											
Other (Specify)											
Cardiac	Cardiac Adult										Note 12
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
Other (Specify)											
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11,12
	Other (Specify)										

N = new indication; P = previously cleared by K090276

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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 12 AHP

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 510(k) Number K093531

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 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	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. (Superficial)											
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 K090276

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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

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510(k) Number K093531

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **BE9-4 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 K090276

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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

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510(k) Number K093531

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 (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					
	Abdominal					P					
	Intra-operative (Note 6)					P					
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric					P					
	Small Organ (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. (Superficial)										
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 K090276

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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

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 Division of Reproductive, Abdominal,
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 510(k) Number K093531

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 (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					
	Abdominal					P					
	Intra-operative (Note 6)					P					
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric					P					
	Small Organ (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. (Superficial)										
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)										

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- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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

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510(k) Number K093531

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 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. (Superficial)											
Intra-vascular		P	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 K090276

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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

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Division of Reproductive, Abdominal,
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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

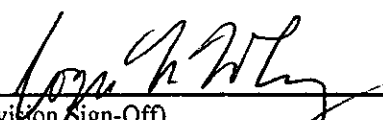
Device Name: **AcuNav 10F Intracardiac Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**
Intended Use: **Diagnostic imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 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		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. (Superficial)										
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 K090276

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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

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510(k) Number K093531

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. (Superficial)										
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 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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

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510(k) Number K093531

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

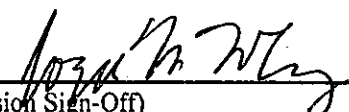
Device Name: **4V1c Phased Sector Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**
Intended Use: **Diagnostic imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation									
Other (Track 1 Only)	Specific (Tracks 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	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 2,3,5,6,7,8,9, 11
	Small Organ (Note 1)										
	Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,5,6,7,8,9, 11
	Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,5,6,7,8,9, 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 2,3,5,6,7,8,9, 11
	Cardiac Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,5,6,7,8,9, 11
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	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 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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 12 AHP

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and Radiological Devices
510(k) Number K093531

Prescription Use (Par 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **YF13-5SP 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 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)		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. (Superficial)		P	P	P			P	P		BMDC	Note 2,3,4,5,7,8,9,11
Intra-vascular												
Other (Specify)												
Cardiac	Cardiac Adult										Note 12	
	Cardiac Pediatric											
	Intra-vascular (Cardiac)											
	Trans-esophageal (Cardiac)											
	Intra-cardiac											
	Other (Specify)											
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11,12	
	Other (Specify)											

N = new indication; P = previously cleared by K090276

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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 12 AHP

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Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

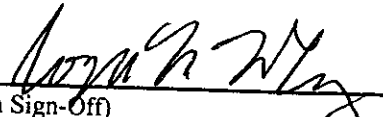
Device Name: **C8-5 Tightly Curved Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**
Intended Use: **Diagnostic imaging or fluid flow analysis of the human body as follows:**

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. (Superficial)		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 K090276

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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

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Division of Reproductive, Abdominal,
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510(k) Number K093531

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 5)										
	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. (Superficial)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9
Intra-vascular											
Other (Specify)											
Cardiac	Cardiac Adult										Note 12
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,12
	Other (Specify)										

- N = new indication; P = previously cleared by K090278
- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
 - Note 2 Ensemble tissue harmonic imaging
 - Note 3 3D imaging
 - Note 4 B&W SieScape panoramic imaging
 - Note 5 Power SieScape panoramic imaging
 - Note 6 For example: abdominal, vascular
 - 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 12 AHP

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510(k) Number K093531

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. (Superficial)											
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 K090276

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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

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Division of Reproductive, Abdominal,
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510(k) Number K093531

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 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 2,3,4,5,7,8,9,11
	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
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 K090276

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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

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510(k) Number K093531

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 K090276

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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

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510(k) Number K093531

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. (Superficial)		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 K090276

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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

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510(k) Number K093531

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 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 2,3,4,5,7,8,9,11
	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. (Superficial)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11
Intra-vascular											
Other (Specify)											
Cardiac	Cardiac Adult										Note 12
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Specify)										
Peripheral Vessel	Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,9,11,12
	Other (Specify)										

N = new indication; P = previously cleared by K090276

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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 12 AHP

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510(k) Number K093531

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 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	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 K090276

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093531

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 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 2,3,4,5,7,8,9,11
	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 K090276

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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

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510(k) Number K093531

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)
Fetal Imaging & Other	Ophthalmic										
	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. (Superficial)										
	Intra-vascular		P	P	P	P	P	P	P		BMDC
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 K090276;

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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

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 510(k) Number K093531

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)										
	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.)										
	Musculo-skel. (Superficial)										
Intra-vascular											
Other (Specify)											
Cardiac	Cardiac Adult										
	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										
	Other (Specify)										

N = new indication; P = previously cleared by K090276

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
- Note 4 B&W SieScape panoramic imaging
- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
- 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

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 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K093531

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **P4-2 Litho 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										
	Abdominal		N	N	N		N	N		BMDC	Note 2,3,4,5,7,8,9, 11
	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. (Superficial)										
Intra-vascular											
Other (Specify)											
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intra-vascular (Cardiac)										
	Trans-esophageal (Cardiac)										
	Intra-cardiac										
	Other (Cardiac Neonatal)										
Peripheral Vessel	Peripheral vessel										
	Other (Specify)										

N = new indication; P = previously cleared by FDA

- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
- Note 3 3D imaging
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- Note 5 Power SieScape panoramic imaging
- Note 6 For example: abdominal, vascular
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Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

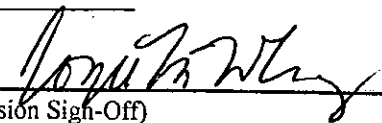
Device Name: **BP9-4 Convex Array Transducer for use with:
ACUSON X300 Diagnostic Ultrasound Systems**
Intended Use: **Diagnostic Imaging or fluid flow analysis of the human body as follows:**

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											
	Abdominal											
	Intra-operative (Note 6)											
	Intra-operative (Neuro)											
	Laparoscopic											
	Pediatric											
	Small Organ (Note 1)		N	N	N			N	N		BMDC	Note 2,3,4,5,7,8,9,11
	Neonatal Cephalic											
	Adult Cephalic											
	Trans-rectal		N	N	N			N	N		BMDC	Note 2,3,4,5,7,8,9,11
	Trans-vaginal											
	Trans-urethral											
	Trans-esoph. (non-Card.)											
	Musculo-skel. (Convent.)											
	Musculo-skel. (Superficial)											
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)											

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- Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
- Note 2 Ensemble tissue harmonic imaging
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