K063803
JAN - 5 2007

510(K) SUMMARY

ACUSON ANTARES™ Diagnostic Ultrasound System

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

1. **Submitted By:**
   Siemens Medical Solutions USA, Inc., Ultrasound Division
   1230 Shorebird way
   Mountain View, CA 94043

   Contact Person:
   Michaela Mahl
   Regulatory Affairs Specialist
   Phone: (650) 694 5653
   FAX: (650) 943 7053

   Date Prepared:
   12/01/2006

2. **Proprietary Name:**
   ACUSON ANTARES™ Ultrasound System

   Common/ Usual Name:
   Diagnostic Ultrasound System with Accessories

   Classification Name:

   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

3. **Predicate Device:**
   - K063138, 11/22/2006, ACUSON Antares™ Diagnostic Ultrasound System
   - K050034, 01/13/2005, SONOLINE Antares™ Diagnostic Ultrasound System
   - K033196, 10/16/2003, SONOLINE Antares™ with CLARIFY VE Diagnostic Ultrasound System

4. **Device Description:**

   The ANTARES system is a multi-purpose diagnostic ultrasound system with accessories and proprietary software.

   The ACUSON ANTARES has been designed to meet the following product safety standards:

   - UL 60601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety
   - CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment

- NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
- EN 60601-1
- EN 60601-1-1
- EN 60601-1-2
- EN 60601-1-2-37
- EN 60601-1-4
- IEC 61157 Declaration of Acoustic Power
- ISO 10993 Biocompatibility
- The system's acoustic output is in accordance with ALARA principle (as low as reasonably achievable)

5. **Intended Uses:**
The Antares ultrasound imaging system is intended for the following applications: Abdominal, Intraoperative, Small Parts, Transcranial, OB/GYN, Cardiac, Intracardiac, Transesophageal, Pelvic, Neonatal/Adult Cephalic, Vascular, Intravascular, Musculoskeletal, Superficial Musculoskeletal, Great Vessel, and Peripheral Vascular applications.

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

6. **Technological Comparison to Predicate Device:**
The ACUSON ANTARES™ is substantially equivalent to the predicate devices listed in paragraph 3 above. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures to aid in diagnosis.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JAN - 5 2007

Re: K063803
Trade Name: ACUSON Antares Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: December 21, 2006
Received: December 22, 2006

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 Antares Diagnostic Ultrasound System as described in your premarket notification:

Transducer Model Number

CW2	PX4-1 Phased Array
CW5	CH6-2 Curved Array
C5-2 Curved Array	CH4-1 Curved Array
CX5-2 Curved Array	PH4-1 Phased Array
VF7-3 Linear Array	P10-4 Phased Array
EC9-4 Curved Array	VF13-5SP Linear Array
VFX9-4 Linear Array	C5F1 Curved Array Mechanical 3D
VF10-5 Linear Array	C7F2 Curved Array Mechanical 3D
VF13-5 Linear Array	EV9F4 Curved Array
VFX13-5 Multi-D Array	V5Ms Multiplane TEE

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 determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Andrew Kang (240) 276-3666.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K063803

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative (Note 9)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Neurological		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ (Note 1)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Cardiac		P	P	P	P	P	P		BMDC	Note 2,3,4,5,6,7,8,10
Trans-esophageal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,6,10
Transrectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Other (specify)										

N = new indication; P = previously cleared by FDA - K063138, K050034, K033196; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging (cardiac only)
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 9 For example: vascular, abdominal
Note 10 Clarify VE vascular enhancement technology

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063803

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): **K063803**

Device Name: **CW2 Probe for use with ACUSON Antares**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal					P					
Abdominal					P					
Intraoperative (Note 9)					P					
Intraoperative Neurological										
Pediatric					P					
Small Organ (Note 1)					P					
Neonatal Cephalic					P					
Adult Cephalic					P					
Cardiac					P					
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel					P					
Laparoscopic										
Musculo-skeletal Conventional					P					
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 9 For example: vascular, abdominal

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063803

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): **K063803**

Device Name: **CW5 Probe for use with ACUSON Antares**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal					P					
Abdominal					P					
Intraoperative (Note 9)					P					
Intraoperative Neurological										
Pediatric					P					
Small Organ (Note 1)					P					
Neonatal Cephalic					P					
Adult Cephalic					P					
Cardiac					P					
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel					P					
Laparoscopic										
Musculo-skeletal Conventional					P					
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 9 For example: vascular, abdominal

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Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063803

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K063803

Device Name: **C5-2 Curved Array Transducer for use with ACUSON Antares**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D Imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063803

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K063803

Device Name: **CX5-2 Curved Array Transducer for use with ACUSON Antares**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

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Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063803

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): **K063803**

Device Name: **VF7-3 Linear Array Transducer for use with ACUSON Antares**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D Imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063803

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): **K063803**

Device Name: **EC9-4 Curved Array Transducer for use with ACUSON Antares**
Intended Use: Ultrasound Imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

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Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063803

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K063803

Device Name: **VFX9-4 Linear Array Transducer for use with ACUSON Antares**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

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Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063803

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K063803

Device Name: **VF10-5 Linear Array Transducer for use with ACUSON Antares**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063803

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): **K063803**

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063803

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K063803

Device Name: **VFX13-5 Multi-D Array Transducer for use with ACUSON Antares**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063803

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): **K063803**

Device Name: **PX4-1 Phased Array Transducer for use with ACUSON Antares**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ										
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Cardiac		P	P	P	P	P	P		BMDC	Note 2,3,4,5,6,7,8,10
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging (cardiac only)
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063803

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): **K063803**

Device Name: **CH6-2 Curved Array Transducer for use with ACUSON Antares**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D Imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

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Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063803

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K063803

Device Name: **CH4-1 Curved Array Transducer for use with ACUSON Antares**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA - K033196; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic Imaging
Note 10 Clarify VE vascular enhancement technology

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Nancy C Brogdon
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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063803

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): **K063803**

Device Name: **PH4-1 Phased Array Transducer for use with ACUSON Antares**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ										
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

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Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063803

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K063803

Device Name: **P10-4 Phased Array Transducer for use with ACUSON Antares**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ										
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac		P	P	P	P	P	P		BMDC	Note 2,3,4,5,6,7,8,10
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional		P	P	P	P	P	P		BMDC	Note 2,3,4,5,7,8,10
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 6 Cadence contrast agent imaging (cardiac only)
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

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Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063803

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): **K063803**

Device Name: **VF13-5SP Linear Array Transducer for use with ACUSON Antares**

Indications For Use: Diagnostic Imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Note 9)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Neurological		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 9 For example: vascular, abdominal
Note 10 Clarify VE vascular enhancement technology

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063803

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): **K063803**

Device Name: **C5F1 Curved array mechanical 3D transducer for use with ACUSON Antares**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon Prescription Use (Per 21 CFR 801.109)
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063803

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K063803

Device Name: **C7F2 Curved array mechanical 3D transducer for use with ACUSON Antares**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8,10
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034, K033196; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D Imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging
Note 10 Clarify VE vascular enhancement technology

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063803

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): **K063803**

Device Name: **EV9F4 Curved Array Transducer for use with ACUSON Antares**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5,7,8
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA - K050034; E = added under Appendix E

Additional Comments:

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 SieClear multi-view spatial compounding
Note 4 Tissue Equalization Technology
Note 5 3-Scape real-time 3D imaging
Note 7 B&W SieScape panoramic imaging
Note 8 Power SieScape panoramic imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063803

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known): K063803

Device Name: **V5Ms Multiplane TEE Transducer for use with ACUSON Antares**
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal		P	P	P	P	P	P		BMDC	Note4
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA - K063138; E = added under Appendix E

Additional Comments:

Note 4 Tissue Equalization Technology

(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)

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