SECTION 11

510(k) Summary

Prepared 10/11/2006

NOV 2 2 2006

Sponsor: Siemens Medical Solutions USA, Inc.,
Ultrasound Division
1230 Shorebird Way
P.O. Box 7393
Mountain View, California 94039-7393

Contact Person: Sheila W. Pickering
Telephone: (650) 943 7187
Fax: (650) 943 7053

Submission Date: October 13, 2006

Device Name: Siemens Antares 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

A. Legally Marketed Predicate Devices
The Siemens Antares Ultrasound system is substantially equivalent to the following:

- K052894, K033196, K023729, 1/1/2005, Antares Diagnostic Ultrasound System
- K052021, 8/17/2005, Siemens V5M Transesophageal Transducer
- K011252, 5/30/2001, GE Hitachi EUB 8500 with Sonoelastography

B. Device Description:

The Siemens Acuson ANTARES MODIFICATION 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, 1998 Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, 1998 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
- IEC 1157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

C. Intended Use

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.

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 modifications to the Antares are verified and validated according to the company's design control process as certified in the 510(k) Notification.

SECTION 11

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- 93/42/EEC Medical Devices Directive

- Safety and EMC Requirements for Medical Equipment
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  - EN/IEC 60601-1-1
  - EN/IEC 60601-1-2
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D. Substantial Equivalence

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E. Performance Data

The modifications to the Antares are verified and validated according to the company's design control process as certified in the 510(k) Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sheila Pickering, Ph.D.
Senior Director of Regulatory Affairs
Siemens Medical Solutions USA, Inc.
P.O. 7393, 1230 Shorebird Way
MOUNTAIN VIEW CA 94039

NOV 2 2 2006

Re: K063138
Trade Name: Siemens ACUSON Antares Modification™ 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 IYX
Dated: October 13, 2006
Received: October 23, 2006

Dear Dr. Pickering:

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 Siemens ACUSON Antares Modification™ Ultrasound System, as described in your premarket notification:

Transducer Model Number

C5-2 Convex Array
C6-2 Convex Array

C8-5 Convex Array
5.0C50+ Convex Array
C6-3 3D Mechanically Driven 3D Convex Array
EV9-4 Convex Array Endovaginal
Endo-VII Mechanical Sector Endovaginal
Endo-V 3D Mechanical Sector Endovaginal
EC9-4 Convex Array Endovaginal
BE9-4 Convex Array Endocavity
5.0L45 Linear Array
7.5L70 Linear Array
LB5-2 Linear Array
L10-5 Linear Array
VF13-5 Linear Array
VF13-5SP Linear Array
7.5L50I Linear Array
7.5L50Q Linear Array
8L3 Linear Array
C7F2 Curved Array
LAP8-4 Laparoscopic
P4-2 Phased Sector Array
5.0P10 Phased Array
MPT7-4 Phased Sector Array TEE
CW2 Continuous Wave Doppler
CW5 Continuous Wave Doppler
P9-4 Phased Sector Array
CH5-2 Convex Array
V5M 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 Sundar Rajan at (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)

SECTION 7

Intended Use of the Device

(ACUSON ANTARES ™ Ultrasound System)

Intended Use:

The Acuson 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 and for analysis packages that provide information that is used for clinical diagnosis purposes.

Prescription Use ✓

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

SIEMENS ACUSON ANTARES MODIFICATION™ 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
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Intraoperative (Note 6)		P	P	P		P	P		BMDC	Note 3
Intraoperative Neurological		P	P	P		P	P		BMDC	Note 2,3
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Small Organ (Note 1)		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2,3
Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2
Cardiac		P	P	P	P	P	P		BMDC	Note 2,7
Transesophageal		P	P	P	P	P	P		BMDC	Note 2,3,7
Transrectal		P	P	P		P	P		BMDC	Note 2,3,4,5
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Laparoscopic		P	P	P		P	P		BMDC	Note 3
Musculo-skeletal (Conventional)		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Musculo-skeletal (Superficial)		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Other (specify)										

P = previously cleared by the FDA under # K052894) E = added under Appendix E.

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 Virtual Format

(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
510(k) Number K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **C5-2** Convex Array Transducer for use with:
SIEMENS ACUSON ANTARES MODIFICATION 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		BMDC	Note 2,3,4,5,
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,
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,
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (Specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **C6-2** Convex Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION 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		BMDC	Note 2,3,4,5,7
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,7
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **C8-5** Convex Array Transducer for use with:
SIEMENS ACUSON ANTARES MODIFICATION 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										
Abdominal		P	P	P		P	P		BMDC	Note 3,4,5
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 3,4,5
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 3,4,5
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 3,4,5
Adult Cephalic										
Cardiac		E	E	E		E	E		BMDC	Note 3,4,5,7
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P		P	P		BMDC	Note 3,4,5
Musculo-skeletal (Superficial)		E	E	E		E	E		BMDC	Note 3,4,5
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **5.0C50+** Convex Array Transducer for use with: **SIEMENS ACUSON ANTARES MODIFICATION 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 3,4,5
Abdominal		P	P	P	P	P	P		BMDC	Note 3,4,5
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 3,4,5
Small Organ (Note 1)		P	P	P	P	P	P		BMDC	Note 3,4,5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 3,4,5
Laparoscopic										
Musculo-skeletal (Conventional)		E	E	E	E	E	E		BMDC	Note 3,4,5
Musculo-skeletal (Superficial)		E	E	E	E	E	E		BMDC	Note 3,4,5
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual Format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **C6-3 3D** Mechanically Driven 3D Convex Array Transducer for use with:
SIEMENS ACUSON ANTARES MODIFICATION 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		BMDC	Note 2,3,4,5
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5
Small Organ (Note 1)										
Neonatal Cephalic		E	E	E		E	E		BMDC	Note 2,3,4,5
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **EV9-4** Convex Array Endovaginal Transducer for use with: **SIEMENS ACUSON ANTARES MODIFICATION 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		BMDC	Note 2,3,4,5
Abdominal										
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P		P	P		BMDC	Note 2,3,4,5
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **Endo-VII** Mechanical Sector Endovaginal Transducer for use with: **SIEMENS ACUSON ANTARES MODIFICATION 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						BM	Note 3
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic		P	P						BM	Note 3
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P						BM	Note 3
Transvaginal		P	P						BM	Note 3
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **Endo-V 3D** Mechanical Sector Endovaginal Transducer for use with:
SIEMENS ACUSON ANTARES MODIFICATION 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						BM	Note 3
Abdominal										
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic		P	P						BM	Note 3
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P						BM	Note 3
Transvaginal		P	P						BM	Note 3
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **EC9-4** Convex Array Endovaginal Transducer for use with: **SIEMENS ACUSON ANTARES MODIFICATION 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		BMDC	Note 2,3,4,5
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P		P	P		BMDC	Note 2,3,4,5
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **BE9-4** Convex Array Endocavity Transducer for use with: **SIEMENS ACUSON ANTARES MODIFICATION 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		BMDC	Note 2,3,4,5
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P		P	P		BMDC	Note 2,3,4,5
Transvaginal		P	P	P		P	P		BMDC	Note 2,3,4,5
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **5.0L45** Linear Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION 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										
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Small Organ (Note 1)		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P	P	P	P		BMDC	Note 2,3,4,5
Musculo-skeletal (Superficial)										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **7.5L70** Linear Array Transducer for use with:
SIEMENS ACUSON ANTARES MODIFICATION 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										
Abdominal										
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 3,4,5
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 3,4,5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		E	E	E		E	E		BMDC	Note 3,4,5
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P		P	P		BMDC	Note 3,4,5
Musculo-skeletal (Superficial)		P	P	P		P	P		BMDC	Note 3,4,5
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **LB5-2** Linear Array Transducer for use with:
SIEMENS ACUSON ANTARES MODIFICATION 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		BMDC	Note 4,5
Abdominal		P	P	P		P	P		BMDC	Note 4,5
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **L10-5** Linear Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION 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										
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,8
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,8
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 2,3,4,5,8
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 2,3,4,5,8
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,4,5,8
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P		P	P		BMDC	Note 2,3,4,5,8
Musculo-skeletal (Superficial)		P	P	P		P	P		BMDC	Note 2,3,4,5,8
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: VF13-5 Linear Array Transducer for use with:
SIEMENS ACUSON ANTARES MODIFICATION 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										
Abdominal										
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 3,4,5,8
Small Organ (Note 1)		P	P	P	P	P	P		BMDC	Note 3,4,5,8
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 3,4,5,8
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 3,4,5,8
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P	P	P	P		BMDC	Note 3,4,5,8
Musculo-skeletal (Superficial)		P	P	P	P	P	P		BMDC	Note 3,4,5,8
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

***VF13-5SP** Linear Array Transducer for use with:*

SIEMENS ACUSON ANTARES MODIFICATION 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										
Abdominal										
Intraoperative (Note 6)		P	P	P		P	P		BMDC	Note 3,4,5,8
Intraoperative Neurological		P	P	P		P	P		BMDC	Note 3,4,5,8
Pediatric		P	P	P		P	P		BMDC	Note 3,4,5,8
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 3,4,5,8
Neonatal Cephalic		P	P	P		P	P		BMDC	Note 3,4,5,8
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 3,4,5,8
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 3,4,5,8
Musculo-skeletal Superficial		P	P	P		P	P		BMDC	Note 3,4,5,8
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **7.5L50I** Linear Array Transducer for use with: **SIEMENS ACUSON ANTARES MODIFICATION 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										
Abdominal		P	P	P		P	P		BMDC	Note 3,4,5
Intraoperative (Note 6)		P	P	P		P	P		BMDC	Note 3,4,5
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 3,4,5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 3,4,5
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 3,4,5
Musculo-skeletal Superficial										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **7.5L50Q** Linear Array Transducer for use with:
SIEMENS ACUSON ANTARES MODIFICATION 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										
Abdominal		P	P	P		P	P		BMDC	Note 3,4,5
Intraoperative (Note 6)		P	P	P		P	P		BMDC	Note 3,4,5
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)		P	P	P		P	P		BMDC	Note 3,4,5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 3,4,5
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P		P	P		BMDC	Note 3,4,5
Musculo-skeletal (Superficial)										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **8L3** Linear Array Transducer for use with:

Siemens Acuson ANTARES MODIFICATION 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										
Abdominal		P	P	P	P	P			BMDC	Note 2,3,4,5,8
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 2,3,4,5,8
Small Organ (Note 1)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,8
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2,3,4,5,8
Laparoscopic										
Musculo-skeletal (Conventional)		P	P	P	P	P	P		BMDC	Note 2,3,4,5,8
Musculo-skeletal (Superficial)										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

C7F2 Curved array mechanical 3D transducer for use with

Siemens Acuson ANTARES MODIFICATION 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		BMDC	Note 2,3,4,5,7
Abdominal		P	P	P		P	P		BMDC	Note 2,3,4,5,7
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,4,5,7
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
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		BMDC	Note 2,3,4,5,7
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

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Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogan

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **LAP8-4** Laparoscopic Transducer for use with:
SIEMENS ACUSON ANTARES MODIFICATION 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										
Abdominal										
Intraoperative (Note 6)		P	P	P		P	P		BMDC	Note 3,4,5
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic		P	P	P		P	P		BMDC	Note 3,4,5
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **P4-2** Phased Sector Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION 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	
Abdominal		P	P	P	P	P	P		BMDC	Note 2,3
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic		P	P	P	P	P	P		BMDC	Note 2,3
Cardiac		P	P	P	P	P	P		BMDC	Note 2,3,7
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **5.0P10** Phased Sector Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION 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
Abdominal		P	P	P	P	P	P		BMDC	Note 2
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		BMDC	Note 2
Small Organ (Note 1)										
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2
Adult Cephalic										
Cardiac		P	P	P	P	P	P		BMDC	Note 2,7
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

***MPT7-4** Phased Sector Array TEE Transducer for use with:*

SIEMENS ACUSON ANTARES MODIFICATION 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										
Abdominal										
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal		P	P	P	P	P	P		BMDC	Note 2,3,7
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: CW2 Continuous Wave Doppler Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION 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										
Abdominal										
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					P					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

CW5 Continuous Wave Doppler Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION 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										
Abdominal										
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric										
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel					P					
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P = previously cleared by the FDA under # K040060; E = added under Appendix E.

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 Virtual format

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)
Diagnostic Ultrasound Indications for Use Form

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063138

510(k) Number (if known):

Device Name:

P9-4 Phased Sector Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION 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
Abdominal		P	P	P	P	P	P		BMDC	Note 2
Intraoperative (Note 6)										
Intraoperative Neurological		P	P	P		P	P		BMDC	Note 2
Pediatric		P	P	P	P	P	P		BMDC	Note 2
Small Organ (Note 1)		P	P	P	P	P	P			
Neonatal Cephalic		P	P	P	P	P	P		BMDC	Note 2
Adult Cephalic		P	P	P	P	P	P			
Cardiac		P	P	P	P	P	P		BMDC	Note 2,7
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC	Note 2
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P = previously cleared by the FDA under # K050240; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name:

CH5-2 Convex Array Transducer for use with:

SIEMENS ACUSON ANTARES MODIFICATION 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		BMDC	Note 2,3,7,8
Abdominal		P	P	P		P	P		BMDC	Note 2,3,7,8
Intraoperative (Note 6)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P		BMDC	Note 2,3,7,8
Small Organ (Note 1)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P		P	P		BMDC	Note 2,3,7,8
Laparoscopic										
Musculo-skeletal (Conventional)										
Musculo-skeletal (Superficial)										
Other (specify)										

P = previously cleared by the FDA under # K043016; E = added under Appendix E.

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 Virtual format

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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 K063138

Diagnostic Ultrasound Indications for Use Form

510 (k) Number (if known):

Device Name:

Acuson Antares Diagnostic Ultrasound System

Transducer: V5M TEE

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	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other : Harmonic Imaging	Other : 3D
Ophthalmic											
Fetal											
Abdominal		N	N	N	N	N	N		N*	N	N
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		N	N	N	N	N	N		N	N	N
Small Organ (Specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		N	N	N	N	N	N		N*	N	N
Trans-esophageal		N	N	N	N	N	N		N*	N	N
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)***											

N = new indication; P = previously cleared by FDA (K032114); E = added under Appendix E

Additional Comments:

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

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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 K063132