K072266

AUG 2 9 2007

510(k) Summary
Siemens Medical Solutions Siemens P50 ™ Ultrasound System

1. SPONSOR

Siemens Medical Solutions
Ultrasound Division
1230 Shorebird Way
Mountain View, California

Contact Person: Sheila W. Pickering Ph.D.
Regulatory Affairs

Telephone: 650 943 7187

Date Prepared: July 31 2007

2. DEVICE NAME

Proprietary Name: Acuson P50 ™ Ultrasound System

Common/Usual Name: Diagnostic Ultrasound System

Classification Name: Diagnostic Ultrasound Transducer
(21 CFR 892.1570, 90-ITX)
Ultrasonic Pulsed Echo Imaging System
(21 CFR 892.1560, 90-IYO)
Diagnostic Ultrasonic Transducer
(21 CFR 892.1570, 90-ITX)

3. PREDICATE DEVICES

K992505	TERATECH Model 2000 Imaging System
K010833	TERATECH Model 8C4 Endocavity Smart Probe
K012191	TERATECH Model 2000 Handheld Ultrasound System with Doppler and Harmonic Imaging Modes
K030191	SIEMENS ™ Model 2000/BAS Portable Ultrasound Systems
K040840	TERATECH Model 10V5 Smart Probe
K043278	TERATECH Model 8IOC4, 8IOL4, and 10LAP4 Probes
K051334	TERASON™ Ultrasound System with Continuous Wave (CW) Doppler and add-to-file submissions

K072266
page 2 of 2

4. INTENDED USE

The Acuson P50 ™ Ultrasound System is intended for diagnostic ultrasound imaging or fluid flow analysis of the human body; specific indications for use are tabulated in Section 4.3 of this submission.

5. DEVICE DESCRIPTION

The Acuson P50 ™ Ultrasound System is identical to the Teratech 2000 and previous Teratech models as identified in the predicate device section.

	TERATECH 2000	Acuson P50
Hardware	Specified in K051334	No change
Transducers	Specified in K051334	Increase number of transducers
Software	Specified in K051334	No change
Labeling	Specified in K051334	Changed only to reflect additional transducers

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The Siemens P50 ™ Ultrasound System is substantially equivalent to the Teratech devices listed above which are currently in commercial distribution in the United States. It is equivalent in modes of operation, and intended for the same clinical applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

AUG 2 9 2007

Re: K072266
Trade/Device Name: Acuson P50™ Ultrasound System
Regulation Number: 21 CFR §892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, IYN, ITX
Dated: August 14, 2007
Received: August 15, 2007

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 P50 Ultrasound System, as described in your premarket notification:

Transducer Model Number

4V2 Phased Array	7L3 Linear Array	12HL7 Hockeystick Linear Array
12L5 Linear Array	AuxCW 2MHz Pedof	

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please 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 Mr. Paul Hardy 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

Enclosures

Attachment 1

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ACUSON P50 Ultrasound System
Transducer: (see comments)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N[d]	N	N		N[d]	N	N[d]
	Abdominal	N[d]	N	N		N[d]	N	N[d]
	Intra-operative (Spec.)[e]	N[d]	N	N		N[d]	N	N[d]
	Intra-operative (Neuro)	N	N	N		N	N	N
	Laparoscopic							
	Pediatric	N[d]	N	N		N[d]	N	N[d]
	Small Organ (Thyroid, Breast, Testes, etc.)	N[d]	N	N		N[d]	N	N[d]
	Neonatal Cephalic	N	N	N	N	N	N	N
	Adult Cephalic	N	N	N	N	N	N	N
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	N[d]	N	N		N[d]	N	N[d]
	Musculo-skel. (Superfic)	N[d]	N	N		N[d]	N	N[d]
	Intra-luminal	N	N	N	N	N[d]	N	N
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N[f]	N	N[g]	N	N
	Cardiac Pediatric	N	N	N[f]	N	N[g]	N	N
	Trans-esoph. (Cardiac)	N	N	N[f]	N	N[g]	N	N
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N[d]	N	N		N	N	N[d]
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD) and (non-directional) Power Doppler.
[b] B+M; B+PWD; B+CWD; B+CD; B+PD.
[c] Harmonic Imaging (HI)
[d] Includes ultrasound guidance for placement of needles & catheters.
[e] Abdominal organs and peripheral vessel.
[f] PW includes PW Doppler Tissue Imaging (DTI).
[g] includes Doppler Tissue Imaging (DTI) .
Includes uses in military field settings in addition to hospital/clinic settings.
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation
✓ Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072264

System: ACUSON P50 Ultrasound System
Transducer: 4V2 Phased Array (K063085)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P[d]	P	P		P[d]	P	P[d]
	Abdominal	P[d]	P	P		P[d]	P	P[d]
	Intra-operative (Spec.)[e]	P[d]	P	P	P	P[d]	P	P[d]
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P[d]	P	P	P	P[d]	P	P[d]
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	P	P	P	P	P	P	P
	Adult Cephalic:	P	P	P	P	P	P	P
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD) and (non-directional) Power Doppler.
[b] B+M; B+PWD; B+CWD; B+CD; B+PD.
[c] Harmonic Imaging (HI)
[d] Includes ultrasound guidance for placement of needles, catheters.
[e] Abdominal organs and peripheral vessel.
[f] PW includes PW Doppler Tissue Imaging (DTI).
[g] Includes Doppler Tissue Imaging (DTI) .
Includes uses in military field settings in addition to hospital/clinic settings.
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072260

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ACUSON P50 Ultrasound Systems
Transducer: 7L3 Linear Array (K042055)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)[e]	P[d]	P	P		P[d]	P	P[d]
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)	P[d]	P	P		P[d]	P	P[d]
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P[d]	P	P		P[d]	P	P[d]
	Musculo-skel. (Superfic)	P[d]	P	P		P[d]	P	P[d]
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P[d]	P	P		P[d]	P	P[d]
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD) and (non-directional) Power Doppler.
[b] B+M; B+PWD; B+CWD; B+CD; B+PD.
[c] Harmonic Imaging (HI)
[d] Includes ultrasound guidance for placement of needles, catheters.
[e] Abdominal organs and peripheral vessel.
[f] PW includes PW Doppler Tissue Imaging (DTI).
[g] includes Doppler Tissue Imaging (DTI) .
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation
✓ Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072266

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ACUSON P50 Ultrasound Systems
Transducer: 12HL7 Hockeystick Linear Array (K051334)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)[e]	P[d]	P	P		P[d]	P	P[d]
	Intra-operative (Neuro)	P	P	P		P	P	P
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)	P[d]	P	P		P[d]	P	P[d]
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P[d]	P	P		P[d]	P	P[d]
	Musculo-skel. (Superfic)	P[d]	P	P		P[d]	P	P[d]
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P[d]	P	P		P[d]	P	P[d]
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD) and (non-directional) Power Doppler.
[b] B+M; B+PWD; B+CWD; B+CD; B+PD.
[c] Harmonic Imaging (HI)
[d] Includes ultrasound guidance for placement of needles, catheters.
[e] Abdominal organs and peripheral vessel.
[f] PW includes PW Doppler Tissue Imaging (DTI).
[g] includes Doppler Tissue Imaging (DTI) .
Includes uses in military field settings in addition to hospital/clinic settings.
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072266

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ACUSON P50 Ultrasound Systems
Transducer: 12L5 Linear Array (K051334)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)[e]	P[d]	P	P		P[d]	P	P[d]
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)	P[d]	P	P		P[d]	P	P[d]
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P[d]	P	P		P[d]	P	P[d]
	Musculo-skel. (Superfic)	P[d]	P	P		P[d]	P	P[d]
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P[d]	P	P		P[d]	P	P[d]
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD) and (non-directional) Power Doppler.
[b] B+M; B+PWD; B+CWD; B+CD; B+PD.
[c] Harmonic Imaging (HI)
[d] Includes ultrasound guidance for placement of needles, catheters.
[e] Abdominal organs and peripheral vessel.
[f] PW includes PW Doppler Tissue Imaging (DTI).
[g] includes Doppler Tissue Imaging (DTI) .
Includes uses in military field settings in addition to hospital/clinic settings.
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation
✓Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072266

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ACUSON P50 Ultrasound Systems
Transducer: AuxCW 2MHz Pedof (K063085)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)[e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD) and (non-directional) Power Doppler.
[b] B+M; B+PWD; B+CWD; B+CD; B+PD.
[c] Harmonic Imaging (HI)
[d] Includes ultrasound guidance for placement of needles, catheters.
[e] Abdominal organs and peripheral vessel.
[f] PW includes PW Doppler Tissue Imaging (DTI).
[g] includes Doppler Tissue Imaging (DTI) .
Includes uses in military field settings in addition to hospital/clinic settings.
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation
✓ Prescription Use (Per 21 CFR 801.1

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072266