K072365

4.2.13b 510(k) Summary/Statement Certification

510(k) Summary
Prepared September 17, 2007

OCT 17 2007

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

Contact Person: Robert F. Lawrence
Telephone: (650) 943 5984
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Submission Date: September 17, 2007

Device Name: Sequoia™ Plus Ultrasound System

Common Name: Diagnostic Ultrasound System

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 Sequoia™ Plus Ultrasound System is substantially equivalent to the Siemens Acuson Sequoia Ultrasound System.

B. Device Description:

The Siemens Sequoia™ Plus has been designed to meet the following product safety standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
  - EN/IEC 60601-1
  - EN/IEC 60601-1-1
  - EN/IEC 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

C. Intended Use

The Sequoia Plus ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal Cardiac, Pediatric, Transespohageal, Adult Cephalic, Peripheral Vessel, Intraoperative Neurological, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications.

The system also provides the ability to measure anatomical structures and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

The typical examinations performed using the Sequoia™ Plus Ultrasound System are:

Cardiac Imaging Applications and Analysis

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

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

Vascular Imaging Applications and Analysis

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

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

Superficial Imaging Applications

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

Intraoperative Imaging Applications

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

Transcranial Imaging Applications

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

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

D. Substantial Equivalence

The submission device is substantially equivalent to the predicate Acuson Sequoia™ previously cleared under K063085 and K051139 with regard to both intended use and technological characteristics.

E. Performance Data

The Sequoia™ Plus is designed, verified, and validated according to the company's design control process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2007

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

Re: K072365
Trade/Device Name: Sequoia™ Plus Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: August 22, 2007
Received: August 23, 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 Sequoia™ Plus Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

9L4
V5M TEE
4V1c
AUX CW2
4Z1c

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, M.D. at (240) 276-3666.

Sincerely yours,

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): K072365

Device Name: **Sequoia™ Plus Diagnostic Ultrasound System**

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

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

N=new indication.

Additional Comments:

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

**neonatal cardiac

(PLESE 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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072365

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K072365
Device Name: **9L4**

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

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

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

Additional Comments:

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

Previously Cleared in 510(k) K063085

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072365

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K072365
Device Name: V5M TEE

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

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

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

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

Previously Cleared in 510(k) K063085, K022567

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072365

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K072365
Device Name: 4V1c

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

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

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

Additional Comments:
*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE
**neonatal cardiac
Previously Cleared in 510(k) K063085, K022567

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072365

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K072365
Device Name: AUX CW2

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

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

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

Additional Comments:
Previously Cleared in 510(k) K063085, K001400

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072365

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known): K072365
Device Name: 4Z1c

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

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

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

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

Previously Cleared in 510(k) K051139

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072365