K051139

510(k) Summary of Safety and Effectiveness

Sequoia Diagnostic Ultrasound System

MAY 13 2005

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

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

   Contact Person:
   Iskra Mraković
   Manager, Regulatory Affairs
   Telephone:(650) 694-5004
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   Date Prepared:
   April 18, 2005

2. **Proprietary Name:**
   Sequoia Diagnostic Ultrasound System

   Common Name:
   Diagnostic Ultrasound System with Accessories

   Classification Name:
   21 CFR 892.1550

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

3. **Predicate Devices:**

   - # K041319 (June 7, 2004), cleared as Sequoia Diagnostic Ultrasound System.
   - #K022303 (July 30, 2002), cleared as Philips M2424 Diagnostic Ultrasound System with 21315 ultrasound transducer.

- #K041552 (July 2, 2004), cleared as GE Vivid 7Diagnostic Ultrasound System with EchoPAC BT04.

4. Device Description:

The Sequoia with Real Time 3D Imaging is substantially equivalent to the predicates listed herein. The Sequoia is a general purpose, mobile, software-controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bioeffect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PWD) Doppler Mode, Continuous (CWD) Doppler Mode, Color Doppler Mode, Power (Amplitude) Doppler Mode, a combination of these modes, Harmonic Imaging, 3D imaging, or Clarify VE imaging, and Real Time 3D Imaging.

The Sequoia Diagnostic Ultrasound System has been designed to conform to the following *product safety standards*:

- UL 60601-1, Medical Electrical Equipment, Part 1: General Requirements for Safety
- CSA C22.2 No. 60601-1, Safety Requirements for Medical Equipment
- NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- 93/42/EEC Medical Device Directive
- Safety and EMC Requirements for Medical Equipment
- EN 60601-1
- EN 60601-1-1
- EN 60601-1-2
- ISO 10993 Biocompatibility
- The system's acoustic output is in accordance with ALARA principle (as low as reasonably achievable)

5. Intended Uses:

The Sequoia platform is intended for use in the following applications:

General Imaging and Cardiology for Fetal, Abdominal, Intraoperative (abdominal and neurological), Pediatrics, Small Organs (breast, testes, thyroid, penis and prostate), Neonatal/Adult Cephalic, Cardiac (adult, pediatric, and neonatal), Trans-esophageal, Transrectal, Transvaginal, Peripheral Vessel, and Musculo-sceletal (superficial and conventional) applications, and intended uses as defined in the FDA guidance document.

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

6. Technological Comparison to Predicate Devices:

The Sequoia is substantially equivalent in its technologies and functionality to the Sequoia Diagnostic Ultrasound System that is already cleared under 510(k) premarket notification number K041319, Philips's M2424 Diagnostic Ultrasound System with 21315 ultrasound transducer (#K022303), and GE's Vivid 7Diagnostic Ultrasound System with EchoPAC BT04 (#K041552).

The Sequoia functions in the same manner as other diagnostic ultrasound systems, in that they transmit ultrasonic energy into the body *via* a transducer. In the body, acoustic impedance of different tissues reflect different amounts of ultrasound energy back to the transducer, where post processing of received echoes is performed to generate two-dimensional *or three-dimensional* on-screen images of anatomic structures and fluid flow within the body. Doppler principles are used to process reflected ultrasound energy to display moving blood as a spectrum, or as color-coded two-dimensional images. All predicate devices listed above, allow for specialized measurements of structures and flow, and provide various calculations' functions.

End of 510(k) Summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Siemens Medical Solutions, USA, Inc.
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 53313

MAY 13 2005

Re: K051139
Trade Name: ACUSON Sequoia Diagnostic Ultrasound System
Regulation Number: 21 CFR §892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Product Code: IYN
Regulation Number: 21 CFR §892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Product Code: IYO
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Product Code: ITX
Regulatory Class: II
Dated: May 2, 2005
Received: May 4, 2005

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 Sequoia Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

Apollo

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 (301) 443-6597 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. Rodrigo C. Perez, at (301)594-1212.

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

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **Apollo**

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)*	Other: Harmonic Imaging	Other: 3D	Other: Real Time 3D
Ophthalmic												
Fetal		N	N	N	N	N	N		N*	N		N
Abdominal		N	N	N	N	N	N		N*	N		N
Intraoperative Abdominal		N	N	N	N	N	N		N*	N		N
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
Trans-esophageal												
Transrectal												
Transvaginal												
Transurethral												
Peripheral Vessel		N	N	N	N	N	N		N*	N		N
Laparoscopic												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
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

**small organs (breast, testes, thyroid, penis, prostate)

***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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051139

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **Sequoia 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)	Other: Harmonic Imaging	Other: 3D	Other: Real Time 3D
Ophthalmic												
Fetal		P	P	P	P	P	P		P*	P	P	N
Abdominal		P	P	P	P	P	P		P*	P	P	N
Intraoperative Abdominal		P	P	P	P	P	P		P*	P	P	N
Intraoperative Neurological		P	P	P	P	P	P		P*	P	P	
Pediatric		P	P	P	P	P	P		P*	P	P	N
Small Organ (specify)**		P	P	P	P	P	P		P*	P	P	
Neonatal Cephalic		P	P	P	P	P	P		P*	P	P	
Adult Cephalic		P	P	P	P	P	P		P*	P	P	
Cardiac		P	P	P	P	P	P		P*	P	P	N
Trans-esophageal		P	P	P	P	P	P		P*	P	P	
Transrectal		P	P	P	P	P	P		P*	P	P	
Transvaginal		P	P	P	P	P	P		P*	P	P	
Transurethral												
Intravascular												
Peripheral Vessel		P	P	P	P	P	P		P*	P	P	N
Laparoscopic											P	
Musculo-skeletal Conventional		P	P	P	P	P	P		P*	P	P	
Musculo-skeletal Superficial		P	P	P	P	P	P		P*	P	P	
Other (specify)***		P	P	P	P	P	P		P*	P	P	N

P=previously cleared by the FDA under K041319, K032114, K022567, K002807, K992631, K992580, K9973767 and K935595/S1.
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

**small organs (breast, testes, thyroid, penis)

***neonatal cardiac

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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 [illegible]
and Radiological
510(k) Number K051139