AUG 1 6 2004

SECTION 11

510(k) Summary of Safety and Effectiveness

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

Contact Person: Patrick Lynch
Regulatory Affairs
Telephone: 425-557-1825
Fax: 425-391-9198

Submission Date: July 23, 2004

Device Name: Cypress Ultrasound System

Common Name: Diagnostic Ultrasound System with Accessories

Classification:

Regulatory Class: II
Review Category: Tier II

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	90-DQO

Predicate Devices:

- # K021497 (July 9, 2002) cleared as ACUSON Cypress™ Ultrasound System.
- # K032114 (July 21, 2003) cleared as ACUSON Sequoia™ Diagnostic Ultrasound System.

Device Description:

The Cypress system is a multi-purpose diagnostic ultrasound system with accessories and proprietary software, and is substantially equivalent to our current product that is already cleared for USA distribution under the following 510(k) Premarket Notification number:

- # K021497 (July 9, 2002) cleared as ACUSON Cypress™ Ultrasound System.

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

- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-2, 1998, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- AIUM/NEMA UD-3, 1998, 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, Safety Requirements for Medical Equipment
  - EN 60601-1-2
  - EN 60601-1-2-37
- ISO 10993 Biocompatibility
- The system's acoustic output is in accordance with ALARA principle (as low as reasonably achievable)

Intended Use:

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

General Imaging and Cardiology for Fetal, Abdominal, Intraoperative (cardiac), Pediatrics, Neonatal Cephalic, Cardiac (adult, pediatric), Trans-esophageal, Peripheral Vessel, Intra-luminal and Intra-cardiac 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.

Technological Comparison to Predicate Device:

The Cypress is substantially equivalent in its technologies and functionality to the Cypress Ultrasound System that is already cleared under 510(k) premarket notification number K021497.

The Cypress 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 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2004

Mr. Patrick Lynch
Regulatory Affairs
Siemens Medical Solutions USA, Inc.
1230 Shorebird Way, P.O. Box 7393
MOUNTAIN VIEW CA 94039-7393

Re: K042055
Trade Name: ACUSON Cypress™ 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: 90 IYN, IYO, and ITX
Dated: July 23, 2004
Received: July 30, 2004

Dear Mr. Lynch:

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 Cypress™ Ultrasound System, as described in your premarket notification:

Transducer Model Number

7L3 Linear Array
3V2c Phased Sector Array
7V3c Phased Sector Array

AcuNav Intracardiac Catheter
Aux CW
V5Ms Phased Sector Array
5.0 MHz Biplane TEE
5.0 MHz Monoplane TEE
4C1 Curvilinear Array

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 (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket

notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact 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

Enclosure(s)

SECTION 6

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **ACUSON Cypress Ultrasound System**

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

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

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

Note 1 For example: cardiac
Note 2 Intra-Luminal, Intra-Cardiac
Note 3 Harmonic imaging
Note 4 Contrast agent imaging

(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 K042055

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **7L3** Linear Array Transducer for use with **ACUSON Cypress**

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

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

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

Note 1 For example: cardiac
Note 3 Harmonic imaging
Note 4 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

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042055

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **3V2c** Phased Sector Array Transducer for use with: **ACUSON Cypress**

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

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

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

Note 1 For example: cardiac
Note 3 Harmonic imaging
Note 4 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

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042055

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **7V3c** Phased Sector Array Transducer for use with: **ACUSON Cypress**

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

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

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

Note 1 For example: cardiac
Note 3 Harmonic imaging
Note 4 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

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042055

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **AcuNav** Intracardiac Ultrasound Catheter for use with: **ACUSON Cypress**

Intended Use: For intracardiac and intra-luminal visualization of cardiac and (great vessel anatomy and physiology, and visualization of other devices in the heart - use in right heart only.

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										
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 (Note 2)		P	P	P	P	P	P			

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

Note 2 Intra-Luminal, Intra-Cardiac

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seguine

(Division Sign-Off)
Division of **Reproductive, Abdominal,** and **Radiological Devices**
510(k) Number K042055

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **Aux CW** Transducer for use with:
ACUSON Cypress

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

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

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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 K042055

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known)

Device Name: **V5Ms** Phased Sector Array TEE Transducer for use with: **ACUSON Cypress**

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

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

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Note 1 For example: cardiac
Note 3 Harmonic imaging
Note 4 Contrast agent imaging

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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 K042055

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **5.0 MHz Biplane** TEE Transducer for use with: **ACUSON Cypress**

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Note 1)		P	P	P	P	P	P			Note 3
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P			Note 3,4
Transesophageal		P	P	P	P	P	P			Note 3,4
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

Note 1 For example: cardiac
Note 3 Harmonic imaging
Note 4 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

(Division Sign-Off)
Division of Reproductive, Abdominal,
and **Radiological Devices**
510(k) Number K042055

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **5.0 MHz Monoplane** TEE Transducer for use with: **ACUSON Cypress**

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Note 1)		P	P	P	P	P	P			Note 3
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P			Note 3,4
Transesophageal		P	P	P	P	P	P			Note 3,4
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

Note 1 For example: cardiac
Note 3 Harmonic imaging
Note 4 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

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042055

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **4C1** Curvilinear Array Transducer for use with: **ACUSON Cypress**

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

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

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

Note 1 For example: cardiac
Note 3 Harmonic imaging
Note 4 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

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042055