510(K) SUMMARY

Addition of Tissue Harmonic Imaging to SONOLINE 7XX Diagnostic Ultrasound System

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 Systems, Inc., Ultrasound Group
22010 S.E. 51st Street
Issaquah, WA 98027-7002

Contact Person:
Steve Hesler
Manager of Regulatory Affairs
(425) 557-1629

Date Prepared:
June 14, 1999

2. **Proprietary Name:**
SONOLINE 7XX

Common/ Usual Name:
Diagnostic Ultrasound System with Accessories

Classification Name:
Ultrasonic Pulsed Doppler Imaging System (Product Code 90 IYN, 21 CFR 892.1550)

3. **Predicate Device:**
K945773, 8/7/95, cleared as the Versa, marketed as the SONOLINE Versa Pro and SONOLINE Sienna
SONOLINE Elegra with THI Imaging (K981528, cleared 10/29/98)

4. **Device Description:**
The SONOLINE 7XX 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 ultrasound data and display it in B-Mode, M-Mode, Color Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, or in a combination of modes, on a CRT display.

The SONOLINE ® 7XX, has been designed to meet the following product safety standards:

- UL 2601, Safety Requirements for Medical Equipment
- CSA 22.2 No. 601-1, Safety Requirements for Medical Equipment
- Standard for Real Time Display of Thermal and Mechanical Indices on Diagnostic Ultrasound Equipment, AIUM/NEMA, 1992.
- 93/42/EEC Medical Devices Directive
- EN60601 = (IEC 601-1-1 + IEC 601-1-2), Safety and EMC Requirements for Medical Equipment

5. **Intended Uses:**
The SONOLINE 7XX ultrasound imaging system is intended for the following applications: General Radiology, Abdominal, Intraoperative, Small Parts, Transcranial,

OB/GYN, Pelvic, Neonatal/Adult Cephalic, Urology, Vascular, Musculoskeletal. Superficial Musculoskeletal, and Peripheral Vascular applications. The addition of THI Imaging will not add new indications for use to the 7XX.

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 Device:**
SONOLINE 7XX is a previously cleared device. The purpose of this submission is to receive clearance for the addition of THI to the already-cleared system. THI is already cleared on another Siemens system, the SONOLINE Elegra.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 1999

Steve Hesler
Manager of Regulatory Affairs
Siemens Medical Systems, Inc.
22010 S. E. 51st Street
Issaquah, WA 98029-7002

Re: K992046
SONOLINE 7XX Diagnostic Ultrasound System (Addition of Harmonic Imaging Option)
Dated: June 14, 1999
Received: June 17, 1999
Regulatory Class: II
21 CFR 892.1550/Procode: 90 IYN
21 CFR 892.1560/Procode: 90 IYO

Dear Mr. Hesler:

We have reviewed your Section 510(k) 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 SONOLINE 7XX Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number(s)

2.5 P20	3.5 C40+	5.0 L45

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 **REVIEWER** at (301) 594-1212.

Sincerely yours,

for David G. Hyman

CAPT Daniel Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Attachment 3

Ultrasound Device Indications Statement

Note: Indications for use are unchanged from what was originally submitted to FDA for both the Versa Pro and the Versa Plus. The table below represents a compilation of all applications for all transducers cleared for use with the Versa family of products. The Versa family currently includes the SONOLINE Sienna and the SONOLINE Versa Plus.

510 (k) Number (if known): K962142 (May 29, 1997), K9945773 (August 7, 1995)

Device Name : SONOLINE Versa Family of Diagnostic Ultrasound Systems

Indications For Use: Diagnostic ultrasound imaging and Doppler analysis of the human body as follows:

(Applications which do not apply are heavily shaded)

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

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

Other Indications or Modes: _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K992046

510 (k) Number (if known) K962142 (May 29, 1997)

Device Name : 2.5P20 transducer for use with SONOLINE 7XX

Indications For Use: Diagnostic ultrasound imaging and Doppler analysis of the human body as follows:

(Applications which do not apply are heavily shaded)

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Tissue Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal		E	E	E	E	E	E		BMDC (E)	N
Intraoperative Abdominal										
Neurosurgical										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic		P	P	P	P	P	P		BMDC (P)	N
Adult Cephalic		P	P	P	P	P	P		BMDC (P)	N
Cardiac		P	P	P	P	P	P		BMDC (P)	N
Transesophageal										
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**

Other Indications or Modes: _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K992046

510 (k) Number (if known) K962142 (May 29, 1997)

Device Name : 3.5C40+ transducer for use with SONOLINE 7XX

Indications For Use: Diagnostic ultrasound imaging and Doppler analysis of the human body as follows:

(Applications which do not apply are heavily shaded)

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Tissue Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		BMDC (P)	N
Abdominal		P	P	P	P	P	P		BMDC (P)	N
Intraoperative Abdominal										
Neurosurgical										
Pediatric		P	P	P	P	P	P		BMDC (P)	N
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
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

Other Indications or Modes: _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use (Per 21 CFR 801.109)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K992046

510 (k) Number (if known) K962142 (May 29, 1997)

Device Name : 5.0L45 transducer for use with SONOLINE 7XX

Indications For Use: Diagnostic ultrasound imaging and Doppler analysis of the human body as follows:

(Applications which do not apply are heavily shaded)

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

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

Other Indications or Modes: _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use (Per 21 CFR 801.109)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K992046