APR 2 4 1998

K980557

510(K) SUMMARY

SONOLINE Elegra 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
(206) 557-1629

Date Prepared:
February 6, 1998

2. **Proprietary Name:**
SONOLINE Elegra Advanced
SONOLINE Elegra

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:**
Siemens SONOLINE Elegra Ultrasound System (K945072), 11/21/95

4. **Device Description:**
The SONOLINE Elegra 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 ELEGRA, 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 Elegra 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 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 Elegra is a previously cleared device. The purpose of this submission is to receive clearance for the indication of Superficial Musculoskeletal imaging. This indication is equivalent to the small parts imaging indication for which the system is already cleared.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 24 1998

Steve C. Hesler
Siemens Medical Systems, Inc.
22010 S.E. 51st St.
Issaquah, WA 98029-7002

Re: K980557
Sonoline® Elegra Diagnostic Ultrasonic System
Dated: February 12, 1998
Received: February 13, 1998
Regulatory class: II
21 CFR 892.1550/Procode: 90 IYN
21 CFR 892.1560/Procode: 90 IYO
21 CFR 892.1570/Procode: 90 ITX

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 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. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducer intended for the Superficial Musculoskeletal application with the Sonoline® Elegra Diagnostic Ultrasonic System, as described in your premarket notification:

Transducer Model Number

7.5L40 Linear Array Transducer

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.

Please be advised that the determination above is based on the fact that no medical devices have been demonstrated to be safe and effective for in vitro fertilization or percutaneous umbilical blood sampling, nor have any devices been marketed for these uses in interstate commerce prior to May 28, 1976, or reclassified into class I (General Controls) or class II (Special Controls). FDA considers devices specifically intended for in vitro fertilization and percutaneous umbilical blood sampling to be investigational, and subject to the provision of the investigational device exemptions (IDE) regulations, 21 CFR, Part 812. Therefore, your product labeling must be consistent with FDA's position on this use.

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 Paul Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for David A. Jefferson

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K980557

Ultrasound Device Indications Statement

510 (k) Number (if known)
:

Device Name : **7.5L40 Linear Array Transducer**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

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

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

Additional Comments: _____

(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)

David A. Segerman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K980557

K980557

Ultrasound Device Indications Statement

510 (k) Number (if known)

Device Name : **SONOLINE Elegra**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

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

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

Additional Comments: _____

(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)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980557