K981626

MAY 27 1998

510(K) SUMMARY

Addition of 3 D Imaging to 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
(425) 557-1629

Date Prepared:
March 31, 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:**
K945072, 11/21/95, cleared as the Q4000, marketed as the SONOLINE Elegra Advanced
K950517, 4/5/96, cleared as Q64XX, marketed as the SONOLINE Elegra
K961833, 10/29/96, SieScape panoramic display for SONOLINE Elegra Advanced

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 addition of 3-D Imaging will not add new indications for use to the Elegra. It will allow the user to display regions of interest in 3-dimensional format, either by showing views in three orthagonal planes or allowing surface rendering of objects.

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 addition of 3 dimensional imaging to the already-cleared system. This real-time reconstruction technique is equivalent to the SieScape panaoramic imaging feature already cleared by 510(k) (see K961833, 10/29/96).

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 1998

Siemens Medical Systems, Inc.
Ultrasound Group
c/o Joseph P. Murnane
Underwriters Laboratories, Inc.
1285 Walt Whitman Road
Melville, New York 11747-3081

Re: K981626
Sonoline® Elegra Diagnostic
Ultrasound System
Dated: May 1, 1998
Received: May 7, 1998
Regulatory class: II
Procodes: 90 IYN, 21 CFR 892.1550
90 IYO, 21 CFR 892.1560
90 ITX, 21 CFR 892. 1570

Dear Mr. Murnane:

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 (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.

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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) 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 the 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) 594-4613. 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 (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

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

Ultrasound Device Indications Statement

510 (k) Number (if known) :

Device Name : **SONOLINE Elegra with SieScape and 3 D Imaging**

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										
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 G. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981626

Ultrasound Device Indications Statement

510 (k) Number (if known) :

Device Name : **2.0 CW probe**

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					
Abdominal					P					
Intraoperative (Specify)					P					
Pediatric					P					
Small Organ (Specify)					P					
Neonatal Cephalic					P					
Adult Cephalic					P					
Cardiac					P					
Transesophageal										
Transrectal					P					
Transvaginal					P					
Transurethral										
Intravascular										
Peripheral vessel					P					
Laparoscopic										
Musculo-skeletal Conventional					P					
Musculo-skeletal Superficial										
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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981626

Ultrasound Device Indications Statement

510 (k) Number (if known) :

Device Name : **2.5PL20 Phased 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		E	E	E	E	E	E		BMDC (E)	
Abdominal		E	E	E	E	E	E		BMDC (E)	
Intraoperative (Specify)										
Pediatric		E	E	E	E	E	E		BMDC (E)	
Small Organ (Specify)										
Neonatal Cephalic		E	E	E	E	E	E		BMDC (E)	
Adult Cephalic		E	E	E	E	E	E		BMDC (E)	
Cardiac		E	E	E	E	E	E		BMDC (E)	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		E	E	E	E	E	E		BMDC (E)	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments:_____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K981626

Ultrasound Device Indications Statement

510 (k) Number (if known) :

Device Name : **3.5PL28 Phased 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		P	P	P	P	P	P		BMDC (P)	
Abdominal		P	P	P	P	P	P		BMDC (P)	
Intraoperative (Specify)										
Pediatric		P	P	P	P	P	P		BMDC (P)	
Small Organ (Specify)										
Neonatal Cephalic		P	P	P	P	P	P		BMDC (P)	
Adult Cephalic		P	P	P	P	P	P		BMDC (P)	
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		P	P	P	P	P	P		BMDC (P)	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Hoyson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K981626

Ultrasound Device Indications Statement

510 (k) Number (if known) :

Device Name : **3.5C40 Curved 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		E	E	E		E	E		BMDC (E)	
Abdominal		E	E	E		E	E		BMDC (E)	
Intraoperative (Specify)										
Pediatric		E	E	E		E	E		BMDC (E)	
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		E	E	E		E	E		BMDC (E)	
Laparoscopic										
Musculo-skeletal Conventional		E	E	E		E	E		BMDC (E)	
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments:_____

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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 K981626

Ultrasound Device Indications Statement

510 (k) Number (if known) :

Device Name : **5.0HDPL40 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		P	P	P		P	P		BMDC (P)	
Abdominal		P	P	P		P	P		BMDC (P)	
Intraoperative (Specify)										
Pediatric		P	P	P		P	P		BMDC (P)	
Small Organ (Specify)										
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										
Other (specify)										

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Hegarty

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981626

Ultrasound Device Indications Statement

510 (k) Number (if known) :

Device Name : **5.0C50 Curved 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		P	P	P		P	P		BMDC (P)	
Abdominal		P	P	P		P	P		BMDC (P)	
Intraoperative (Specify)										
Pediatric		P	P	P		P	P		BMDC (P)	
Small Organ (Specify)										
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										
Other (specify)										

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Additional Comments:_____

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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 K981626

Ultrasound Device Indications Statement

510 (k) Number (if known) :

Device Name : **6.5EC10 Curved 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										
Intraoperative (Specify)										
Pediatric										
Small Organ (Specify)		E	E	E		E	E		BMDC (E)	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		E	E	E		E	E		BMDC (E)	
Transvaginal		E	E	E		E	E		BMDC (E)	
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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Additional Comments:_____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Feigal

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981626

Ultrasound Device Indications Statement

510 (k) Number (if known) :

Device Name : **6.5EV13 Curved 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										
Intraoperative (Specify)										
Pediatric										
Small Organ (Specify)		P	P	P		P	P		BMDC (P)	
Neonatal Cephalic		P	P	P		P	P		BMDC (P)	
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P		P	P		BMDC (P)	
Transvaginal		P	P	P		P	P		BMDC (P)	
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:_____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981626

Ultrasound Device Indications Statement

510 (k) Number (if known) :

Device Name : **7.5C30 Curved 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		E	E	E		E	E		BMDC (E)	
Abdominal		E	E	E		E	E		BMDC (E)	
Intraoperative (Specify)										
Pediatric		E	E	E		E	E		BMDC (E)	
Small Organ (Specify)		E	E	E		E	E		BMDC (E)	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		E	E	E		E	E		BMDC (E)	
Laparoscopic										
Musculo-skeletal Conventional		E	E	E		E	E		BMDC (E)	
Musculo-skeletal Superficial										
Other (specify)										

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David G. Hyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981626

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		P	P	P		P	P		BMDC (P)	
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		P	P	P		P	P		BMDC (P)	
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										
Other (specify)										

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

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(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. Peyton

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981626

Ultrasound Device Indications Statement

510 (k) Number (if known) :

Device Name : **7.5PL13 Phased 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		E	E	E	E	E	E		BMDC (E)	
Abdominal		E	E	E	E	E	E		BMDC (E)	
Intraoperative (Specify)										
Pediatric		E	E	E	E	E	E		BMDC (E)	
Small Organ (Specify)		E	E	E	E	E	E		BMDC (E)	
Neonatal Cephalic		E	E	E	E	E	E		BMDC (E)	
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel		E	E	E	E	E	E		BMDC (E)	
Laparoscopic										
Musculo-skeletal Conventional		E	E	E	E	E	E		BMDC (E)	
Musculo-skeletal Superficial										
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. Bergman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981626