

MAY 29 1997

510(K) SUMMARY

K962142

SONOLINE Versa 555 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 SE 51st Street
Issaquah, WA 98027-7002

Contact Person:

Steve Hesler
Manager of Regulatory Affairs
(206) 557-1629

Date Prepared:

May 30, 1996

2. Proprietary Name:

SONOLINE Versa 555 Diagnostic Ultrasound System

Common/ Usual Name:

Diagnostic Ultrasound System with Accessories

Classification Name:

Ultrasonic Pulsed Doppler Imaging System (Product Code 90 YIN, 21 CFR 892.1550)

3. Predicate Device:

Siemens SONOLINE Versa Diagnostic Ultrasound System (K945773), 8/7/95.
Siemens SONOLINE Elegra Diagnostic Ultrasound System (K945072),
11/21/95.

4. Device Description:

The SONOLINE Versa 555 is a general purpose, mobile, software-controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical values related to potential bioeffect mechanisms. Its function is to acquire ultrasound data and display it in B-Mode, M-Mode, Color Flow Modes, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, or in a combination of modes, on a CRT display.

The SONOLINE ® Versa 555 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.
- 93/94/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 Versa 555 ultrasound imaging system is intended for the following applications: **General Radiology, Abdominal, Intraoperative (abdominal and neurosurgical), Small Parts, Transcranial, OB/GYN, Pelvic, Neonatal Cephalic, Urology, Vascular, Peripheral Vascular, and Transesophageal Echocardiography (TEE) 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:**

The SONOLINE Versa 555 is similar to the SONOLINE Versa in that both incorporate software controlled electronics to transmit ultrasonic pulses, via a transducer, into a patient, then receive return (echo) pulses and to convert those pulses into a visual display, to be provide information for use in the diagnosis of various disease states as well as normal conditions such as pregnancy and physical development. The operating principles of both systems are identical. However, the SONOLINE Versa 555 supports phased array transducers.

Both systems incorporate an on-screen display of Mechanical (MI) and Thermal (IT) Indices, in compliance with the Standard for Real Time Display of Thermal and Mechanical Indices on Diagnostic Ultrasound Equipment, AIUM/NEMA, 1992.

End of 510(k) Summary



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 1997

Steve Hesler
Manager Regulatory Affairs
Siemens Medical Systems
22010 S.E. 51st St.
Issaquah, WA 98027-7002

Re: K962142
Sonoline Versa 555
Dated: April 10, 1997
Received: April 11, 1997
Regulatory class: II
21 CFR 892.1550/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 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 transducers intended for use with the Sonoline Versa 555, as described in your premarket notification:

Transducer Model Number

2.5 MHZ 2.5P20 Phased Linear Array
3.5 MHZ 3.5P14 Phased Linear Array
3.5 MHZ 3.5C20 Curved Array
3.5 MHZ 3.5C40 Curved Array
3.5 MHZ 3.5C60 Curved Array
3.5 MHZ 3.5C80 Curved Array
5.0 MHZ TEE
5.0 MHZ 5.0P10 Phased Linear Array
5.0 MHZ 5.0L45 Linear Array
5.0 MHZ 5.0C50 Curved Array

5.0 MHZ 5.0L90 Linear Array
6.5 MHZ 6.5F13 Curved Array
6.5 MHZ 6.5EV13 Curved Array
7.5 MHZ 7.5C30 Curved Array
7.5 MHZ 7.5L40 Linear Array
7.5 MHZ 7.5L50I Linear Array
7.5 MHZ 7.5L50Q Linear Array
7.5 MHZ 7.5L70 Linear Array
10.0 MHZ 10.0L25 Linear Array

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 for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 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 February 17, 1993 "Revised 510(k) Diagnostic Ultrasound Guidance for 1993." 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:

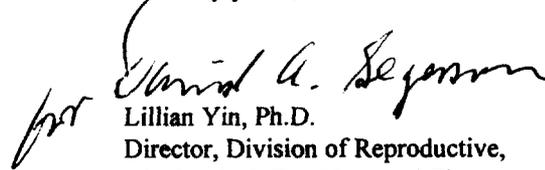
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 "dsma@fdadr.cdrh.fda.gov".

If you have any questions regarding the content of this letter, please contact Maureen Butler at (301) 594-1212.

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

Enclosure(s)

Ultrasound Device Indications Statement

510 (k) Number (if known)

K962142

Device Name

2.5P20 transducer for use with the SONOLINE Versa 555

Indications For Use

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

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	C (Color Maps)	Combined (B,C,D)	Other (Specify)
Ophthalmic							
Fetal							
Abdominal							
Intraoperative							
Abdominal							
Neurosurgical							
Pediatric							
Small Organ							
Cephalic	√	√	√	√	√	√	
Adult							
Neonatal							
Cardiac	√	√	√	√	√	√	
Adult							
Pediatric							
Trans-esophageal							
Trans-rectal							
Trans-vaginal							
Intra-luminal							
Trans-urethral							
Peripheral vessel							
Laparoscopic							

(Other Indications or Modes)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Donald G. Segerson
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number: K962142