

K962 882

510(K) SUMMARY

SONOLINE ® Versa Pro Diagnostic Ultrasound System, Addition of 6.5 MHz Laparoscopic Probe

APR 24 1997

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.

- Submitted By:**
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Date Prepared:
July 22, 1996

- Proprietary Name:**
SONOLINE Versa Pro 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)

- Predicate Device:**
Siemens SONOLINE Versa Diagnostic Ultrasound System (K945773), 8/7/95.
Tetrad Corp., Laparoscope Ultrasound Transducer (K924204), 6/7/93.

- Device Description:**

The SONOLINE Versa Pro 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 Pro 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 Pro ultrasound imaging system is intended for the following applications: General Radiology, Abdominal, Intraoperative, Small Parts, Transcranial, OB/GYN, Pelvic, Neonatal Cephalic, Urology, Vascular, Peripheral Vascular, and Laparoscopic 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 Pro is identical 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.

The Siemens 6.5 MHz Laparoscopic Probe is technologically equivalent to the Tetrad Laparoscope in that both incorporate a linear array transducer of 6.0 MHz center frequency on the end of an articulating arm. Both are intended for intra-abdominal ultrasound examinations via small abdominal incisions.

End of 510(k) Summary