

**510(K) SUMMARY**

OCT 29 1996

**SONOLINE Elegra Diagnostic Ultrasound system with SieScape**

K961833

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:**

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**2. Proprietary Name:**

SONOLINE Elegra Platform 256 Diagnostic Ultrasound System

**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 Platform 256 Diagnostic 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, and Peripheral Vascular applications. The addition of SieScape with Measurements will not change or add to the intended uses above, which are identical to those included in the original submission for the Elegra.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes. The addition of SieScape with Measurements will allow for measurements across a wider field of view than with standard B-mode imaging ultrasound systems.

**6. Technological Comparison to Predicate Device:**

The SONOLINE Elegra incorporating SieScape with Measurements is similar to the SONOLINE Elegra 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 used for diagnosis of various disease states. The operating principles of both systems are the identical. However, the SONOLINE Elegra with SieScape Measurements allows for measurements on larger anatomical features than would be possible with the previously cleared Elegra.

Both systems incorporate an on-screen display of Mechanical (MI) and Thermal (TI) 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**