

MAR 17 1997

Attachment C
SD 800 SW Modification

K970034

510(k) Summary of Safety and Effectiveness: 21 CFR 807.92

1) Submitter's Name / Contact Person: Paul Schrader

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Date Summary was prepared: December 16, 1996

2) Trade Name: SD 800 SonoDiagnost Ultrasound Imaging System

Common Name : Ultrasound Imaging System

Classification Pro Codes: 90 IYN & 90 IYQ

3) Identification of Predicate Device:

The predicate device for this submittal is the existing SD 800 and EV transducer which were reviewed by FDA on the SD 800 system that was submitted as part of K935923.

4) Description of the device or modification being submitted for premarket approval.

Functionality: The new EV transducer has equivalent functionality to the existing transducer now being used.

Scientific Concepts: same as existing EV transducer

Significant Characteristics of the Modification: The new EV transducer has new patient contact materials. It is this change that creates the need to file a 510(k) with the FDA.

The transducer is an existing transducer being sold and marketed by Echo ultrasound. Acoustic performance of the system / transducer combination will be handled as a 510(k) to file based on Appendix I of the February 1993 Ultrasound Guidance.

5) Statement of Intended Use: No change from existing SD 800 platform reviewed during 510(k) 935923.

6) Predicate Device Comparison: There are no significant differences in safety and efficacy between the 21370A and 21370B transducers. A detailed comparison of the transducers can be found in the 510(k) report.