

MAR 19 1997

K963706

**Attachment C**  
SD 800 SW Modification

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

**1) Submitter's Name / Contact Person:** Paul Schrader  
**Address:** 3000 Minuteman Road, Andover Ma. 01810  
**Telephone Number:** 508-659-2404  
**Date Summary was prepared:** August 26, 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 existing SD 800 human interface controls 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:** This SW modification allows for automatic determination of the flow angles used in Doppler and CVI imaging.

**Scientific Concepts:** The automatic flow angle is determined using an algorithm that is described in detail in Appendix C of the 510(k) report.

**Significant Characteristics of the Modification:** Since the flow angle will be set automatically use of this SW modification will reduce the time a sonographer needs to set the angle. The sonographer still has the ability to override the automatic placement if they do not like the automatic angle positioning.

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

**6) Predicate Device Comparison:** The SD 800 already has the ability to manually position the flow angle cursor in the image. The new SW allows this position to automatically be determined by the system. Both sets of SW allow for final manual adjustment of the position.