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PREMARKET NOTIFICATION 510(k)
Cordis Corporation
Avanti + Catheter Sheath Introducer

K970392

APR 24 1997

SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Provisions

Common or Usual Name: Catheter Sheath Introducer or Sheath Introducer System
Proprietary Name: Cordis Avanti + Catheter Sheath Introducer System

II. Name of Predicate Devices

Brite Tip Catheter Sheath Introducer, K 9954595, October 02, 1995
Avanti™ Catheter Sheath Introducer, K 945616, November 14, 1994

III. Classification

Class II

IV. Performance Standards

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

V. Intended Use and Device Description

The Avanti + Catheter Sheath Introducer is indicated for use in arterial and venous procedures requiring percutaneous introduction of catheters and other intravascular devices.

As with other currently marketed Cordis CSIs mentioned in this submission, these devices provide vascular access for various intravascular devices through the valve while simultaneously maintaining hemostasis. Infusion of fluids into the vasculature and withdrawal of blood from the vasculature are possible using the sheath sideport.

VI. Biocompatibility

All appropriate biocompatibility tests were previously performed on the materials used for the Cordis Avanti + Catheter Sheath Introducer. No new tests were performed, since all materials had been successfully tested on previously concurred devices.

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VII. Summary of Substantial Equivalence

The Cordis Avanti + Catheter Sheath Introducer is similar in design, construction, indication for use, and performance characteristics to other commercially available sheath introducers.