

OCT 11 1996

K962746

**Summary of Safety and Effectiveness
Pursuant to Section 513(I) of the Federal Food, Drug, and
Cosmetic Act**

I. General Provisions

Classification Name: Catheter Sheath Introducer (CSI) Kit

Common or Usual Name: Sheath Introducer Kit or Trans-Radial
Introducer Kit

Proprietary Name: Cordis Avanti™ Trans-Radial Sheath
Introducer Kit

Applicant Name and Address: Cordis
P.O. Box 025700
Miami, FL 33015-5700

II. Name of Predicate Devices

Cordis Avanti™ Catheter Sheath Introducer	K945616 and K932733
Cordis Plus Catheter Sheath Introducer	K911794
Arrow Radial Artery Catheterization Set	K810675

III. Classification

Catheter Sheath Introducer Kits are Cardiovascular Diagnostic Devices and are classified as Class II devices according to 21 CFR 870.1340.

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™ Trans-Radial Catheter Sheath Introducer kit is intended for use in (radial) arterial 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 performed on the new material used for the Trans-Radial CSI Kit. All other materials were tested on previously concurred devices and passed.

VII. Summary of Substantial Equivalence

Except for the site of entry (radial instead of femoral) and the addition of the radial vessel dilator and needle (thus making it a complete kit), the Cordis Avanti™ Trans-Radial Catheter Sheath Introducer Kit has the same intended use as other sheath introducers already on the market (i.e., Cordis Avanti™ CSI and Cordis Plus CSI). In addition, the Avanti™ Trans-Radial CSI Kit is similar in its basic design, construction, and indication for use to currently marketed catheter sheath introducer systems.