

**NOV 13 1986**

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**PREMARKET NOTIFICATION  
Cordis Corporation  
ST Steerable Guidewire**

**SUMMARY OF SAFETY AND EFFECTIVENESS**

**I. General Provisions**

Common or Usual Name: Catheter Guide Wire

Proprietary Name: Cordis ST Steerable Guidewire

**II. Name of Predicate Devices**

Cordis WIZDOM Steerable Guidewire (K953760)  
ACS HI-TORQUE FLOPPY/FLOPPY II/Intermediate/Standard Guide Wire  
(K881897)

**III. Classification**

Catheter Guide Wire, Class II - 21 CFR 870.1330  
74DQX - Cardiovascular Devices

**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 Cordis ST Steerable Guidewires are intended for use in angiographic procedures to introduce and position catheters and interventional devices within the coronary and peripheral vasculature.

The Cordis ST Steerable Guidewire incorporates a stainless steel corewire and radiopaque coil. The shaft is coated with PTFE.

**VI. Biocompatibility**

All materials have been tested as specified by the FDA modified matrix of ISO-10993 (Blue Book Memorandum G95-1). All material demonstrated compatibility with biological tissue by meeting the acceptance requirements stipulated in the test protocols.