**PREMARKET NOTIFICATION 510(k)**
**Cordis Corporation**

K960511

**Cordis Guiding Catheter**

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## SUMMARY OF SAFETY AND EFFECTIVENESS

**I. General Provisions**:

Common or Usual Name: Percutaneous Catheter
Proprietary Name: Cordis Vista Brite Tip®

**II. Name of Predicate Devices:**

Cordis Vista Brite Tip
Cordis Endovascular Systems, ENVOY Guiding Catheters

**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. Indication For Use and Device Description**

Indications: Vista Brite Tip: The guiding catheter is intended for use for intravascular introduction of interventional/diagnostic devices into the coronary or peripheral vascular systems.

Description: The Vista Brite Tip Guiding Catheters are single lumen catheters which features a nylon body reinforced with a tightly wound stainless steel braid wire. The braid wire extends from the hub into the Brite Tip segment. The transition segments of the catheters are designed with nylons of different durometer (stiffness) to provide a gradual decrease in material stiffness from the catheter body to the tip. The Brite Tip segment, located at the catheters' tip, is Pellethane® with a radiopaque filler, this is the softest material in the catheter.

**VI. Biocompatibility**:

All appropriate biocompatibility tests for the guiding catheters were successfully completed.

**VII. Summary of Substantial Equivalence**:

The Cordis Guiding Catheters are similar in design, construction, indication for use and performance characteristics to other commercially available guiding catheters.