PREMARKET NOTIFICATION 510(k)
Cordis Corporation

K963962

Cordis Guiding Catheter

SUMMARY OF SAFETY AND EFFECTIVENESS

MAY -7 1997

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, peripheral and neurovasculature.

Description: The Vista Brite Tip Guiding Catheters are single lumen catheters which features a nylon body reinforced with a tightly wound stainless 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 durometers (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.