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PREMARKET NOTIFICATION 510(k)
Cordis Corporation
a Johnson & Johnson Company
Cordis Guiding Catheter
Modifications

SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Provisions:

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

II. Name of Predicate Devices:

Cordis ENVOY, and Cordis Vista Brite Tip

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 and peripheral vascular systems.
ENVOY: The ENVOY Guiding Catheter is intended for use in the peripheral, coronary and neurovasculature for the intravascular introduction of interventional/diagnostic devices.

Description: The ENVOY and 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.

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Section 3 - Proposed Labeling

a) Package Labels:

Draft labeling for the ENVOY and the Vista Brite Guiding Catheters is located in Attachment I.

The Instructions For Use for the ENVOY and the Vista Brite Tip Catheters is located in Attachment I.

Sterile/Caution statement appears on the box and catheter pouch and is identical for the ENVOY and the Vista Brite Tip Guiding Catheters. It is located in Attachment I.

The labeling, IFUs and Sterile/Caution statement are identical to the predicate devices. The only possible modification is the lengths and ID (inner diameters) under the cathetr descriptions

b) Statement of Intended Use: The intedded use is identical to the predicate catheters.

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

ENVOY: The ENVOY Guiding Catheter is intended for use in the peripheral, coronary and neurovasculature for the intravascular introduction of interventional/diagnostic devices.

The indication for use can also be found on the following page pursuant to the FDA requirement, that all 510(k) submitters provide the indication for use on a separate page, in Attachment V, which clearly states, "Indications for Use".

c) Advertisements or Promotional Materials

The product advertisement/promotional materials are located in Attachment I.