K964367

PREMARKET NOTIFICATION 510(k)
Cordis Corporation
CES Vascular Occlusion System

JAN 30 1997

SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Provisions

Common or Usual Name: Occlusion Device or Occlusion Coils or Fibered Microcoils Coil pusher or Embolic Coil Pusher

Proprietary Name: CES Vascular Occlusion System

II. Name of Predicate Devices

Target Therapeutics Fibered Helical Coils (K901721- concurred 07/03/90)

Cook, Inc. Hilal Embolization Microcoil (K901337 - concurred 11/09/90)

Target Therapeutics Helical Coils and Coil Pusher (K891688 - concurred 09/15/89)

Cordis Endovascular Systems (CES), Inc. Instinct® Steerable Guidewire (K930982 - concurred 02/24/94)

III. Classification

Class III

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

CES Occlusion Devices may be used to reduce or block the rate of blood flow in small or tapering vessels. They are indicated for use in the interventional radiologic management of arteriovenous malformations and other vascular lesions of the brain, spinal cord and spine when devascularization prior to definitive surgical resection is desired.

VI. Biocompatibility

All appropriate biocompatibility tests were successfully performed on the CES Occlusion System (occlusion device and coil pusher).

VII. Summary of Substantial Equivalence

The CES Vascular Occlusion System (occlusion device and coil pusher) are similar in their basic design, construction, indication for use and performance characteristics to other commercially available coil occlusion systems.