

PREMARKET NOTIFICATION 510(k)
Cordis Corporation

K972978

Cordis Guiding Catheter

SUMMARY OF SAFETY AND EFFECTIVENESS

OCT 21 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 or peripheral vasculature.

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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 1997

Ms. Katherine Trevisol
Cordis Corporation
14201 N.W. 60th Avenue
Miami Lakes, Florida 33014

Re: K972978
7F 0.078" I.D. Vista Brite Tip Guiding Catheters
Regulatory Class: II (two)
Product Code: 74 DQY
Dated: October 9, 1997
Received: October 10, 1997

Dear Ms. Trevisol:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): To be assigned by FDA

Device Name: Cordis 7F 0.078" I.D. Vista Brite Tip Guiding Catheters

Indications for Use:

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

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IS NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Hematology

510(k) Number K972978

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use