

SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Provisions:

JUL 23 1997

Common Name: Catheter, Percutaneous

Proprietary Name: ENVOY® Guiding Catheter

II. Name of Predicate Device:

a) Trade Name: 5F & 6F ENVOY Guiding Catheters
Manufacturer: Cordis Endovascular Systems, Inc.
510(k) Number: K962362 - concurrence 08/08/96
Predicate for design, intended use, sterilization and packaging

b) Trade Name: 9F Brite Tip Guiding Catheter
Manufacturer: Cordis Corporation
510(k) Number: K925131 - concurrence 05/06/93
Predicate for design

III. Classification:

Class II, Catheter, Percutaneous, 21 CFR 870.1250 (74DQY)

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:

The 7F, 8F and 9F ENVOY Guiding Catheters are designed for the intravascular introduction of interventional/diagnostic devices into the peripheral, coronary and neurovascular systems.

VI. Biocompatibility

All appropriate biocompatibility tests were successfully performed on the Cordis Endovascular Systems, Inc. 7F, 8F and 9F ENVOY Guiding Catheter.

VII. Summary of Substantial Equivalence:

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUL 23 1997

Re: K965247
ENVOY Guiding Catheter
Regulatory Class: II (two)
Product Code: 74 DQY
Dated: April 23, 1997
Received: April 24, 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.

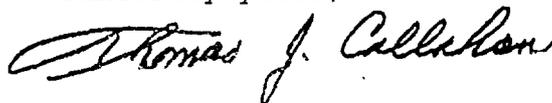
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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

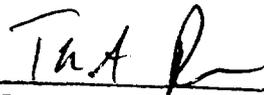
STATEMENT OF INDICATIONS FOR USE

The ENVOY Guiding Catheters are intended for the intravascular introduction of interventional/diagnostic devices in the peripheral, coronary and neurovasculature systems.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K965247

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over The Counter Use _____