

SUMMARY OF SAFETY AND EFFECTIVENESS**I. General Provisions**

JUL 14 1997

Common or Usual Name: Diagnostic, Intravascular Catheter
Proprietary Name: FG Infusion Catheter

II. Name of Predicate Devices

MAGIC Infusion Catheter - K923368
Balt, distributed by Target Therapeutics
Product Code: 74DQO
Predicate for design, intended use and packaging

CES Infusion Catheters - K965181
Cordis Endovascular Systems, Inc.
Product Code: 74KRA
Predicate for design, intended use, sterilization and packaging

EDDY Infusion Catheter
Medi-tech - Boston Scientific Corporation
Product Code: 74KRA
Predicate for design and intended use and packaging

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. Intended Use and Device Description

CES Infusion Catheters are intended to be used as a mechanism for the selective infusion of various diagnostic, embolic and therapeutic agents into the peripheral, coronary and neurovasculatures.

VI. Biocompatibility

Entire FG Infusion Catheters were subjected to biocompatibility testing based on the FDA modified matrix of ISO-10993 (Blue Book Memorandum G95-1). The catheters demonstrated compatibility with biological tissue by meeting the acceptance criteria stipulated in the test protocols.

VII. Summary of Substantial Equivalence

The CES FG Infusion Catheter is substantially equivalent in its basic design, construction, indications for use, performance characteristics, packaging and sterilization to other commercially available infusion catheters.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lisa Wells
Manager, Regulatory Affairs
and Clinical Research
Cordis Endovascular Systems, Inc. JUL 14 1997
P.O. Box 025700
Miami, Florida 33102-5700

Re: K971306
FG Infusion Catheter
Regulatory Class: II (two)
Product Code: KRA
Dated: June 26, 1997
Received: June 30, 1997

Dear Ms. Wells:

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 (Premarket 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) 594-4648. 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

0-000045

510(k) Number: _____

Indications For Use

The CES FG Infusion Catheter is intended to be used as a mechanism for the selective infusion of various diagnostic, embolic and therapeutic agents into the peripheral, coronary and neurovasculatures.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K971306