PREMARKET NOTIFICATION 510(k)
Cordis Corporation
OPTA 5 PTA Catheters
April 18, 1997

K971579

JUL 18 1997

SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Provisions:

Common Name: Percutaneous Transluminal Angioplasty Catheters

Proprietary Name: OPTA 5™ PTA Catheters

II. Name of Predicate Devices:

1. Trade Name: OPTA 5 PTA Catheters
   Manufacturer: Cordis Corporation

2. Trade Name: JUPITER PTA Catheters
   Manufacturer: Cordis Corporation

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:

OPTA 5 PTA Catheters are designed for dilating stenoses in peripheral arteries (iliac, renal, popliteal, infra popliteal, femoral, and ilio femoral).

VI. Biocompatibility

All appropriate biocompatibility tests were successfully performed on Cordis Corporation's OPTA 5 PTA Catheters.

VII. Summary of Substantial Equivalence:

OPTA 5 PTA Catheters are substantially equivalent to the predicate devices. OPTA 5 PTA Catheters are similar in design, construction, indications for use, and performance characteristics as compared to commercially available PTA Catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mirjam Barboza, M.D.
Manager, Regulatory and Clinical Affairs
Cordis Corporation
P.O. Box 025700
Miami, Florida 33102-5700

JUL 18 1997

Re: K971579
Cordis Opta5 PTA Balloon Catheter
Regulatory Class: II (two)
Product Code: LIT
Dated: April 18, 1997
Received: April 21, 1997

Dear Dr. Barboza:

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

INDICATIONS FOR USE

510(k) Number: K971579

Device Name: **Cordis Opta5 PTA Balloon Catheter**

Indications for Use: **The Opta5 catheters are intended for balloon dilatation of lesions in peripheral arteries (iliac, renal, popliteal, infra popliteal, femoral and ilio femoral) and are also intended to treat obstructive lesions of native or synthetic arteriovenous dialysis fistulae.**

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

Prescription Use √ OR Over - the - Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971579