K972825

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OCT - 7

Summary of Safety and Effectiveness

General Provisions	Common Name: Peripheral Transluminal Angioplasty Balloon Catheter Proprietary Name: Opta5 PTA Balloon Catheter Powerflex PTA Balloon Catheter
Name of Predicate Devices	1. Cordis Opta5 PTA Balloon Catheter 2. Cordis Powerflex PTA Balloon Catheter 3. Medi-tech Ultra-thin Diamond Balloon Dilatation Catheter 4. Cordis Palmaz and Palmaz-Schatz Balloon Expandable Stents
Classification	Class II
Performance Standards	Performance Standards have not been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act.
Intended Use and Device Description	Opta5 and Powerflex PTA Balloon Catheters are indicated for dilatation of stenoses in iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. In addition, certain sizes of Opta5 and Powerflex catheters are also indicated for deployment of Palmaz and Palmaz-Schatz balloon expandable Stents for the biliary system.
Bio-compatibility	All appropriate biocompatibility tests were successfully performed on Cordis' Opta5 and Powerflex PTA Balloon Catheters.
Summary of Substantial Equivalence	Opta5 and Powerflex PTA Balloon Catheters are substantially equivalent to the predicate devices. Opta5 and Powerflex PTA Balloon Catheters are similar in design, construction and indications for use compared to commercially available PTA catheters.

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Summary of Safety and Effectiveness (Continued)

A statement of substantial equivalence to another product is required by 21 CFR 807.87, and relates only to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the commissioner of the FDA stated "A determination of substantial equivalence under the Federal Food, Drug and Cosmetic Act related to the fact that the product can be lawfully marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits" 42 Fed. Reg. 42, 50 et seq. (1977).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 7 1997

Mirjam Barboza, M.D.
Manager, Regulatory and Clinical Affairs
Cordis Corporation
14201 N.W. 60th Avenue
Miami Lakes, Florida 33014

Re: K972825
Opta5™ and PowerFlex™ PTA Balloon Catheters
Dated: July 8, 1997
Received: July 9, 1997
Regulatory class: II
21 CFR §876.5010/Product code: 78 FGE

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) 594-4613. 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,

William Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number To be Assigned

Device Name Cordis Opta5 PTA Balloon Catheter
Cordis Powerflex PTA Balloon Catheter

Indications for Use

Opta5 PTA Balloon Catheters are indicated for dilatation of stenoses in iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Powerflex PTA Balloon Catheters are indicated for dilatation of stenoses in iliac, femoral, popliteal and renal arteries.

In addition, certain sizes of Opta5 and Powerflex catheters are also indicated for deployment of Palmaz and Palmaz-Schatz Balloon Expandable Stents for the biliary system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over - The Counter Use _____
(Per 21 CFR 801.109)

Robert P. Mathey
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972825