

# Appendix C

## Summary of Safety and Effectiveness

**Submitter:** Cordis Corporation, a Johnson and Johnson Company  
 40 Technology Drive  
 Warren, New Jersey 07059

Telephone: (908) 755-8300  
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**Contact Person:** Karen Wilk  
 Senior Associate, Regulatory Affairs  
 Cordis Corporation, a Johnson and Johnson Company  
 40 Technology Drive  
 Warren, New Jersey 07059

Telephone: (908) 412-7257  
 Fax: (908) 412-3915

**Date Prepared:** August 20, 1999

**General Provisions** Trade Name: Cordis PowerFlex™ Extreme PTA Balloon Catheter  
 Common Name: Peripheral Transluminal Angioplasty Balloon Catheter  
 Classification Name: CFR 870.1250 Percutaneous Catheter

**Device Classification** Class II.

**Name of Predicate Devices** Cordis PowerFlex™ Plus PTA Balloon Catheter

**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**

The PowerFlex Extreme PTA balloon catheter is 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.

The Cordis PowerFlex Extreme PTA balloon catheter is a dual lumen design with a distal inflatable balloon. Two radiopaque marker bands indicate the dilating section of the balloon and aid in the balloon placement.

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**Biocompatibility:**

All materials used in the PowerFlex Extreme PTA balloon catheter are biocompatible.

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**Performance  
Data:**

The safety and effectiveness of the Cordis PowerFlex Extreme PTA Balloon Catheter have been demonstrated via data collect from non-clinical design verification tests and analyses.

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**Summary of  
Substantial  
Equivalence**

The PowerFlex Extreme PTA Balloon Catheter is substantially equivalent to the previously cleared PowerFlex Plus PTA Balloon Catheters.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 15 1999

Ms. Karen Wilk  
Cordis Corp.  
40 Technology Drive  
Warren, NJ 07059

Re: K992825  
Cordis PowerFlex EXTREME Percutaneous Transluminal  
Angioplasty (PTA) Balloon Catheter  
Regulatory Class: II (two)  
Product Code: 74 LIT  
Dated: August 20, 1999  
Received: August 23, 1999

Dear Ms. Wilk:

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 legally marketed predicate 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.

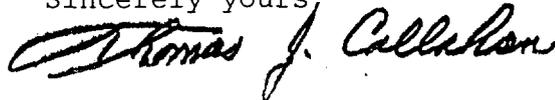
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, 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 pre-market 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) 594-4648. 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/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Thomas J. Callahan". The signature is written in a cursive style with a large, stylized initial 'T'.

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

Enclosure

Special 510(k) Number:

K992825

Device Name:

**Cordis PowerFlex EXTREME Percutaneous Transluminal  
Angioplasty (PTA) Balloon Catheter**

Indication For Use:

The Cordis PowerFlex EXTREME PTA Balloon Catheter is indicated for treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae and to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

Christina M. Alford for Callahan  
(Division Sign-Off)

Division of Cardiovascular and Respiratory Devices

510(k) Number

K992825