

K984214

AUG 10 1999

### 510(k) Summary of Safety and Effectiveness

**Trade Name** The trade name is :  
• Cordis Endovascular Systems, Inc. Temporary Occlusion Balloon Catheter

**Predicate Devices** The predicate devices are listed in the table below:

Device	Company	Product Code	Predicate for:
Prowler Infusion Catheter	Cordis Endovascular Systems, Inc.	74DQO	Intended Use, Sterilization, Manufacturing Process, Packaging, Materials
NDSB Balloon Catheter	Interventional Therapeutics Corporation	74HBZ	Intended Use, Design
NDSB Occlusion Balloon Catheter	Interventional Therapeutics Corporation	74DXC	Intended Use, Design
NDSB Balloon Catheter	Interventional Therapeutics Corporation	74DXC	Intended Use, Design

**Classification** This is a Class II Device.

**Performance Standard** The FDA under Section 514 of the Food, Drug and Cosmetic Act has not established performance standards for this device.

**Intended use** The Temporary Occlusion Balloon Catheter is intended for the temporary occlusion of blood vessels in neuro and peripheral vasculature.

**Performance Testing** In-vitro testing showed that the Temporary Occlusion Balloon Catheter performs similar to the predicate devices as far as:

- Tip linear stiffness
- Catheter kink resistance
- Catheter preparation time
- In-vitro clinical simulation
- Balloon inflation/deflation times
- Deflatability

Animal study testing indicated that the device works as intended.

**Biocompatibility** All appropriate biocompatibility tests were successfully performed on the materials used to manufacture the Temporary Occlusion Balloon Catheter.

*Continued on next page*

## 510(k) Summary of Safety and Effectiveness, Continued

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**Summary of  
Substantial  
Equivalence**

The Temporary Occlusion Balloon Catheter is similar in its basic design, construction, indication for use, and performance characteristics to the predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 10 1999

Ms. Alina Caraballo  
Regulatory Affairs Manager  
Cordis Endovascular Systems, Inc.  
P.O. Box 025700  
Miami Lakes, FL 33102-5700

Re: K984214  
Trade Name: Cordis Endovascular Temporary Occlusion Balloon  
Catheter  
Regulatory Class: II  
Product Code: DXC  
Dated: May 20, 1998  
Received: May 21, 1998

Dear Ms. Caraballo:

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 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) 594-4586. 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" (21CFR 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,



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

Enclosure

510(k) Number: K984214

## Indications for Use Statement

The Temporary Occlusion Balloon Catheter is intended for the temporary occlusion of blood vessels in neuro and peripheral vasculature.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

✓  
Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

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

*Christina M. Alford Callahan*

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

510(k) Number \_\_\_\_\_