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K980653 1/4

510(k) Summary

Submitter: Cordis, a Johnson & Johnson Company
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Date Prepared: February 10, 1998

Trade Name: Cordis PERFLEX Stainless Steel Stent and Delivery System

Common Name: Biliary Stent

Classification Name: Biliary Catheter and Accessories (per 21 CFR 876.5010)

Device Classification: Class II

Summary of Substantial Equivalence:

The design, material, components, method of delivery, and intended use featured with the Cordis PERFLEX Stainless Steel Stent and Delivery System are substantially equivalent to those featured among predecessor Cordis devices (see 510(k) #K905720, #K911581, #K955728, #K964688, and #K972825) and competitive medical devices, such as the

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Schneider WallStent Biliary Transhepatic Endoprosthesis (see 510(k) #K885180, #K896163, #K911292, #K914277, #K923993, #K961262, and #K964119).

In short, the Cordis PERFLEX Stainless Steel Stent and Delivery System represents a line extension to the Cordis Biliary Stent and Delivery System (510(k) #K955728).

Device Description:

The Cordis PERFLEX Stainless Steel Stent and Delivery System consists of the following components:

- The balloon-expandable PERFLEX Stainless Steel Stent;
- A delivery balloon catheter (either the Cordis PowerFlex or OPTA 5 Balloon Catheter, depending on the stent size); and,
- An insertion tool.

The Cordis PERFLEX Stainless Steel Stent and Delivery System features a balloon-expandable, stainless steel, welded wire stent that is delivered by a balloon catheter. The stent is provided premounted upon its associated balloon catheter. The Cordis PowerFlex and OPTA 5 Balloon Catheters are used for the delivery of the PERFLEX Stainless Steel Stents. The Cordis PERFLEX Stainless Steel Stent and Delivery System is advanced over a guidewire through a sheath lumen to an obstruction site in the biliary tree where the balloon is inflated to expand the stent. The balloon is then deflated and removed.

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Also included with the Cordis PERFLEX Stainless Steel Stent and Delivery System is a stainless steel insertion tool that can be placed within the hemostatic valve of a commercially available introducer sheath to protect the stent / balloon catheter assembly during its insertion. Once the stent/balloon assembly passes through the valve, the insertion tool is removed.

The Cordis PERFLEX Stainless Steel Stent and Delivery System is provided sterile and is intended for single use only.

Intended Use:

The Cordis PERFLEX Stainless Steel Stent and Delivery System is intended for use in the palliation of malignant neoplasms in the biliary tree.

Technological Characteristics:

The Cordis PERFLEX Stainless Steel Stent and Delivery System incorporates the same design, components, method of deployment, materials, and intended use as those found among predicate Cordis metal biliary stents (see 510(k) #K955728 and #K964688). The Cordis PERFLEX Stainless Steel Stent is provided in a range of expanded lengths from 16 to 80 mm and in a range of expanded diameters from 7 to 10 mm.

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Performance Data:

The safety and effectiveness of the Cordis PERFLEX Stainless Steel Stent and Delivery System have been demonstrated via data collected from nonclinical tests and analyses.

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 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 Federal Register 42, 50 et seq. (1977).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 1998

Mr. Chuck Ryan
Manager, Regulatory Affairs
Cordis
40 Technology Drive
Warren, NJ 07059

Re: K980653
Cordis PERFLEX Stainless Steel Stent and Delivery System
Dated: May 1, 1998
Received: May 4, 1998
Regulatory Class: II
21 CFR 876.5010/Procode: 78 FGE

Dear Mr. Ryan:

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 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

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

510 (k) Number: _____

Device Name: **Cordis PERFLEX Stainless Steel Stent and Delivery System**

Indications For Use:

The Cordis PERFLEX Stainless Steel Stent and Delivery System is indicated for the palliation of malignant neoplasms in the biliary tree.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Robert R Satterwhite
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K980653