AUG 2 7 2001

510(k)
Summary of Safety and Effectiveness

Submitter:

Cordis Corporation, a Johnson & Johnson Company
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Warren, New Jersey 07059

Contact Person:

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Date Prepared: February 9, 2001

Trade Name: Cordis **PALMAZ® GENESIS™** Transhepatic Biliary Stent and Delivery System

Common Name: Biliary stent and accessories

Classification Name: Biliary catheter and accessories

Device Classification: Class II, per 21 CFR 876.5010

Summary of Substantial Equivalence:
In short, the subject **PALMAZ GENESIS** Transhepatic Biliary Stent and Delivery System represents a line extension to the predicate Cordis BX Transhepatic Biliary Stent and Delivery System (ref. K001258) that includes a "rapid exchange" delivery catheter and a slightly expanded range of stent expanded diameters. This general catheter design is featured with other predicate devices, such as the Guidant RX Megalink SDS Biliary Stent System (ref. K992319) and the Guidant RX Herculink 14 Biliary Stent System (ref. K990867, K993588, and K001224).

Device Description:
The **PALMAZ GENESIS** Transhepatic Biliary Stent is a balloon-expandable, laser cut stent made from 316L stainless steel tubing. The stent is sold mounted on a Cordis percutaneous transluminal angioplasty (PTA) balloon catheter. A .014" guidewire compatible balloon catheter is used as a delivery system for the **PALMAZ GENESIS** Transhepatic Biliary Stent. The catheter has a distal port (hole) approximately 29 cm from the distal tip which accesses the guidewire lumen; the guidewire lumen begins at the distal port and terminates at the distal tip. Two radiopaque marker bands aid in stent placement. A metal introducer tube accessory is also provided.

Intended Use:
The **PALMAZ GENESIS** Transhepatic Biliary Stent and Delivery System is intended for palliation of malignant neoplasms in the biliary tree.

Technological Characteristics:
The subject **PALMAZ GENESIS** Transhepatic Biliary Stent and Delivery System incorporates indications for use, "rapid exchange" design, and dimensional and performance specifications that are substantially equivalent to those found with the aforementioned predicate device. The balloon-expanded, stainless steel stent is provided in a range of expanded diameters from 4 to 7 mm and in nominal lengths of 12-24 mm. The delivery device features nominal balloon lengths in a range of 15-25mm and useable catheter lengths in a range of 75-135cm.

Performance Data:
The safety and effectiveness of the Cordis **PALMAZ GENESIS** Transhepatic Biliary Stent and Delivery System have been demonstrated via data collected from non-clinical tests and analyses, which addressed the following:

- Biocompatibility
- Deployment Testing
- Compression Force Testing
- Dimensional Testing
- Corrosion Testing
- Balloon Performance Testing
- Stent Deformation Testing
- Tensile Strength Testing

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

AUG 2 7 2001

Mr. Charles J. Ryan
Manager, Regulatory Affairs
Cordis Corporation
A Johnson & Johnson Company
40 Technology Drive
Warren, New Jersey 07059

Re: K010411
Cordis Palmaz Genesis Transhepatic Biliary Stent and Delivery System
Regulatory Class: II
21 CFR §876.5010
Product Code: 78 FGE
Dated: May 25, 2001
Received: May 29, 2001

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 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 and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

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.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally §809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. 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, International and Consumer 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,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010411

Device Name: Cordis Palmaz Genesis Transhepatic Billiary Stent and Delivery System

FDA's Statement of the Indications For Use for device:

The Cordis Palmaz Genesis Transhepatic Billiary Stent and Delivery System is indicated for use in the palliation of malignant neoplasms in the biliary tree.

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K010411

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