DEC 2 2 2003

Attachment 1

K033394

Summary of Safety and Effectiveness

Submitter & Contact person:
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Date Prepared **October 22, 2003**

Trade Name Cordis PALMAZ GENESIS Transhepatic Biliary Stent on OPTA PRO .035" Delivery System.

Classification Name & Device Classification
Common Name: Biliary Stent and accessories
Classification Name: 21 CFR 876.5010: Biliary Catheter and Accessories.
Class II; Product Code: 78FGE.

Device description
The **PALMAZ GENESIS** Transhepatic Biliary Stent on **OPTA PRO** .035" Delivery System represents a line extension to the original Cordis premounted PALMAZ GENESIS Transhepatic Biliary Stent on OPTA PRO .035" Delivery System (ref. 510(k) #K012590) with **no** change to the indication for use or to the fundamental scientific technology of the predecessor device.

Stent:
The PALMAZ GENESIS Transhepatic Biliary stent is a balloon expandable, laser cut stent mounted on a Cordis balloon catheter (OPTA PRO) and is currently provided in ten (10) nominal unexpanded stent lengths from 12mm to 79 mm. The stent is designed for expansion to diameters from 4mm to 10 mm, depending on the diameter of the associated balloon upon which it is mounted.

	The PALMAZ Genesis stent is laser cut from a 316L stainless steel tube that meets the chemical analysis requirements of American Society for Testing Materials (ASTM) standard F138. **Delivery system:** The delivery system features the **same** OPTA PRO PTA balloon catheter, which was recently cleared by FDA via 510(k) #K032737, determined substantially equivalent on October 02, 2003), which incorporated this modified hub. **Accessory:** The delivery system features the **same** accessory (a 304 stainless steel Introducer Tube), which is packaged in the device packaging.
Intended Use	The Intended Use has **not** changed and remains as "The Cordis PALMAZ GENESIS Transhepatic Biliary Stent on OPTA PRO .035" Delivery System is indicated for use in the palliation of malignant neoplasms in the biliary tree".
Name of affected device	Cordis PALMAZ GENESIS Transhepatic Biliary Stent on OPTA PRO .035" Delivery System.
Performance standards	The FDA under section 514 of the Food, Drug and Cosmetic Act has not established performance standards for these devices.
Safety and Performance Data	The safety and effectiveness of the affected balloon expandable stent and delivery system has been demonstrated via data collected from non-clinical design verification tests and analyses. All materials used in this modified device have been tested according to ISO–10993, Part 1 and were found biocompatible.
Conclusion	The Cordis **PALMAZ GENESIS** Transhepatic Biliary Stent on **OPTA PRO** .035" Delivery System is substantially equivalent to the predicate original device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 2 2003

Ms. Karen Wilk
Regulatory Affairs Manager
Cordis Corporation
7 Powder Horn Drive
WARREN NJ 07059

Re: K033394
Trade/Device Name: Cordis PALMAZ® GENESIS™ Transhepatic Biliary Stent on OPTA PRO .035" Delivery System
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: November 24, 2003
Received: November 25, 2003

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 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 Section 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 Part 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 Part 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,

Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K033394

Device Name: Cordis PALMAZ® GENESIS™ Transhepatic Biliary Stent on OPTA PRO .035" Delivery System

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

The Cordis PALMAZ® GENESIS™ Transhepatic Biliary Stent on OPTA PRO .035" Delivery System is indicated for use in the palliation of malignant neoplasms in the biliary tree.

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

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033394