510(k) Summary of Safety and Effectiveness

APR 2 7 2006

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FDA Establishment Registration
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Date prepared: March 30, 2006

Trade Name: Cordis Palmaz Blue™ .014 Transhepatic Biliary Stent System

Common Name: Biliary Stent (incl. Accessories)

Classification Name: 21 CFR 876.5010 - Biliary Catheter

Device Classification: Class II

FDA Classification Panel: Gastro-enterology urology

Product Code: FGE

Summary of Substantial Equivalency

Comparison of the new and the predicate devices show that the intended use of the subject device and the predicate devices are identical and that those technological characteristics such as materials, components, biocompatibility, performance properties, dimensions (size range), accessories, method of delivery, fundamental technology (operating principle), packaging configuration and packaging materials, labelling, manufacturing and sterilization processes featured with the Palmaz Blue .014 Transhepatic Biliary Stent System are substantially equivalent to those featured with the currently marketed Cordis Palmaz Blue .018 Transhepatic Biliary Stent System and the currently marketed Palmaz Genesis Transhepatic Biliary Stent on Aviator .014" Delivery System.

With respect to the stent design, materials (Cobalt Chromium-alloy), manufacturing substantially equivalence is claimed to the Cordis Palmaz Blue .018 Transhepatic Biliary Stent System.

Product Description

The Palmaz Blue Transhepatic Biliary Stent is a balloon expandable Cobalt Chromium Biliary stent. The stent is provided premounted on a balloon catheter, i.e., the Cordis Aviator 0.14" Delivery System. The stent and delivery system are advanced over a guidewire through a sheath lumen, via the use of a stainless steel introducer tube accessory, (which is provided together with the Palmaz Blue .014 Transhepatic Biliary Stent System) to an obstruction site in the biliary tree where the balloon is then inflated to expand the stent. After full expansion of the stent, the balloon is then deflated and subsequently the delivery system is removed.

The Palmaz Blue .014 Transhepatic Biliary Stent System is provided sterile (via Ethylene Oxide sterilization) and is intended for single use only.

Intended Use

The Cordis Palmaz Blue .014 Transhepatic Biliary Stent System is indicated for the palliation of malignant neoplasms in the biliary tree.

Performance Standards / Special Controls

There are no performance standards applicable under section 514 of the Food, Drug, and Cosmetic Act for this device. The contents of this 510(k) premarket notification have been prepared based upon the FDA's – Guidance for the content of premarket notifications for metal expandable biliary stents (February 5, 1998).

Summary of Studies

The safety and effectiveness of the device and the substantial equivalence to the predicate devices have been demonstrated via data collected from non-clinical *in-vitro* bench testing and animal testing (stent placement in biliary duct) which was prescribed in the FDA's – Guidance for the content of premarket notifications for metal expandable biliary stents (February 5, 1998).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2006

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

Re: K060877
Trade/Device Name: Cordis PALMAZ® BLUE™ .014 Transhepatic Biliary Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: March 30, 2006
Received: March 31, 2006

Dear Ms. Wilk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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.

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.

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 described above is added to your labeling.

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.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K060877

Device Name: Cordis PALMAZ® BLUE™ .014 Transhepatic Biliary Stent System

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

The Cordis PALMAZ® BLUE™ .014 Transhepatic Biliary Stent System is indicated for the palliation of malignant neoplasms in the biliary tree.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060877