

OCT 29 1999

K993091

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## Attachment 4

### Summary of Safety and Effectiveness

**General Provisions**

The name of the device is:

Proprietary Name	Common or Usual Name
Cordis PALMAZ® XL Transhepatic Biliary Stents	Biliary Stent

**Name of Predicate Devices**

The device is substantially equivalent to:

- Cordis PALMAZ® Balloon Expandable Transhepatic Biliary Stents

**Classification**

Class II.

**Performance Standards**

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

**Indications for Use**

The Cordis PALMAZ® XL Transhepatic Biliary Stents are intended for use in the palliation of malignant neoplasms in the biliary tree.

**Device Description**

The PALMAZ® XL Transhepatic Biliary Stent is a balloon-expandable, laser cut stent made from 316L stainless steel tubing. The stent is supplied in two nominal lengths: 40 mm, and 50 mm. The stent is designed to expand to 10mm diameter. The PALMAZ® XL Transhepatic Biliary Stent is sold unmounted for use with the Cordis POWERFLEX™ PLUS Percutaneous Transluminal Angioplasty (PTA) balloon catheter.

**Biocompatibility**

All materials used in the Cordis PALMAZ® XL Transhepatic Biliary Stents are biocompatible.

Cordis PALMAZ™ XL Transhepatic Biliary Stent  
Special 510(k)  
September, 1999

**Summary of  
Substantial  
Equivalence**

The Cordis PALMAZ® XL Transhepatic Biliary Stents are substantially equivalent to the predicate device. The equivalence was confirmed through pre-clinical testing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 29 1999

Ms. Ariel MacTavish, RAC  
Manager, Regulatory Affairs  
Cordis Corporation  
P.O. Box 025700  
Miami, FL 33102-5700

Re: K993091  
Cordis PALMAZ® XL Transhepatic Biliary Stent  
Regulatory Class: II  
21 CFR 876.5010  
Product Code: 78 FGE  
Dated: October 14, 1999  
Received: October 15, 1999

Dear Ms. MacTavish:

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.

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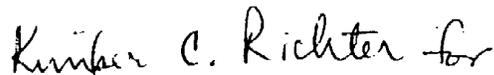
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 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,



David W. Feigal, Jr., M.D., M.P.H.  
Acting Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K993091

Device Name: Cordis PALMAZ® XL Transhepatic Biliary Stent

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

The Cordis PALMAZ® XL Transhepatic Biliary Stent is intended for use in the palliation of malignant neoplasms in the biliary tree.

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

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(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K993091/S<sup>201</sup>