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PALMAZ® GENESIS™ Transhepatic Biliary Stent on .018 SLALOM Delivery System
Cordis Europa, N.V., a Johnson & Johnson Company

510(k) Premarket Notification

Attachment 1

510 (k) Summary

**Submitter's
name and
address**

Cordis Europa, NV
Oosteinde 8
NL-9301 LJ Roden
The Netherlands

Contact Person

Harm Hovinga
Senior Regulatory Affairs Associate
Tel: +31 - (5050) 22479
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Date prepared

April 26, 2002.

**Device Trade
Name**

Cordis **PALMAZ® GENESIS™** Transhepatic Biliary Stent on **SLALOM™** .018"
Delivery System.

Common Name

Biliary stent and accessories

**Classification
Name**

FGE
(21 CFR 876.5010 Biliary Catheter.)

**Device
Classification**

Class II.

**Performance
standards**

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

Product 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 SLALOM percutaneous transluminal angioplasty (PTA) balloon catheter. The stent is provided in nominal, unexpanded stent lengths from 12 – 39 mm. The stent is designed for expansion to diameters from 3 – 8 mm, depending on the diameter of the associated balloon upon which it is mounted with system lengths of 80 cm and 135 cm.

The delivery system utilizes an over-the-wire (OTW) dual lumen design and is a PTA balloon catheter with a distal DURALYN™ balloon and a proximal Y-connector. The balloon has two radiopaque markers that aid in stent placement within the stenosis and is designed with a known diameter and length. The Y-connector has an injectate lumen (marked “THRU”) that is used to inject contrast medium via hand injection and to track the catheter over a guide wire up to .018”. The inflation lumen (marked “BALLOON”) is used to inflate and deflate the balloon with a contrast medium/saline mixture. The nominal balloon size and length is printed on the Y-connector.

A metal introducer tube is included in the packaging.

The **PALMAZ GENESIS** Transhepatic Biliary stent on **SLALOM .018”** Delivery System is provided sterile (via ethylene oxide) and is intended for single use only

Intended Use

The Cordis **PALMAZ GENESIS** Transhepatic Biliary Stent on **SLALOM .018”** Delivery System is intended for use in the palliation of malignant neoplasms in the biliary tree.

Technological comparison

Comparisons of the subject and predicate device shows that technological characteristics, such as materials, mode of operation, performance properties, biocompatibility, sterilization and packaging are substantially equivalent to the currently marketed predicate device, which bears the **same** Tradename “**PALMAZ GENESIS** Transhepatic Biliary stent on **SLALOM .018”** Delivery System”.

Performance Data

The safety and effectiveness of the Cordis **PALMAZ GENESIS** Transhepatic Biliary Stent on **SLALOM .018”** Delivery System has been demonstrated via data collected from non-clinical design verification tests and analyses. As the materials did not change, the materials used are biocompatible.

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 FDA 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. The determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Federal Register 42, 50 et seq. (1977).



JUN 28 2002

Cordis Europa, N.V.
c/o Ms. Karen Wilk
Manager, Regulatory Affairs
Cordis Corporation
7 Powder Horn Drive
WARREN NJ 07059

Re: K021345
Trade/Device Name: PALMAZ® GENESIS™ Transhepatic Biliary Stent
on SLALOM™ .018" Delivery System
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: May 31, 2002
Received: June 3, 2002

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.

Page 2 – Ms. Karen Wilk

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.

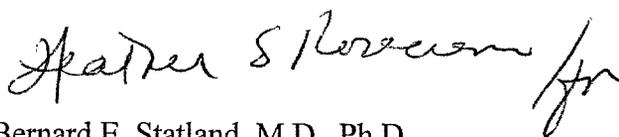
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



Bernard E. Statland, M.D., Ph.D.

Director

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

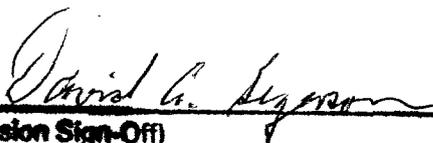
510(k) Number (if known): K021345

Device Name: Cordis PALMAZ® GENESIS™ Transhepatic Biliary Stent
on SLALOM™ .018" Delivery System

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

The Cordis PALMAZ® GENESIS™ Transhepatic Biliary Stent on SLALOM™ .018" Delivery System is intended for 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 K021345