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K964688

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510(k) Summary

Submitter's name: Cordis Corporation, a Johnson & Johnson Company
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Contact person: Joan Martin
Manager, Regulatory Affairs
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Date prepared: November 20, 1996

Trade name: Long Medium PALMAZ-SCHATZ™
Balloon-Expandable Stent

Common name: Biliary Stent

Classification name: §876.5010 Biliary Catheter and Accessories

Predicate devices: PALMAZ™ and PALMAZ-SCHATZ™ Balloon-Expandable Stents

Schneider's Wallstent® Biliary Endoprosthesis

Device description: The Long Medium PALMAZ-SCHATZ™ Balloon-Expandable Stent is a stainless steel, multi-articulated, slotted tube with nominal lengths of 42mm (PS424), 56mm (PS564), and 78mm (PS784) and an expansion range of 6-10mm. The Stents are intended for palliation of malignant neoplasms in the biliary tree. The Stents are provided unmounted to be crimped onto commercially available Cordis Opta 5™ Catheters which have been qualified by Cordis for stent delivery. The Stent is expanded via inflation of the balloon catheter and deployed. Upon expansion, the Stent forms a strong open lattice in a diamond pattern. The expanded Stent conforms to the inner luminal surface of the bile duct. The ability of the Stent to palliate malignant neoplasms is based upon the ability of the metallic structure of the Stent to plastically deform when the balloon is inflated and maintain its expanded state.

Accessory Devices - The following accessory devices have been slightly modified to accommodate the longer Stent lengths. Shorter versions of these devices are

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marketed for use with our current line of biliary stents, as well as with our iliac stent.

The Crimping Tube is constructed of polyethylene. It is supplied sterile, for one use only and is provided with the unmounted Stent. The Crimping Tube protects the Stent/balloon assembly during the manual crimping process. Crimping tube modifications consist of a longer length to accommodate the longer stents and a slightly decreased wall thickness.

The Crimping Tool (CRT 80) is a hand-held, reusable, metallic instrument which is used to manually crimp the unmounted Stents onto the recommended balloon catheter. The Crimping Tool is provided nonsterile and must be sterilized prior to use by standard autoclave procedures. The tool delivers a radial compressive force to the Stent, thereby securing the Stent to the balloon catheter. The Crimping Tool die has been modified to accommodate the additional stent lengths. Our currently marketed Crimping Tool (CRT40) is used to crimp the 42mm Long Medium Stents.

Intended use statement:

The stents are intended for palliation of malignant neoplasms in the biliary tree.

Labeled indication:

The Long Medium PALMAZ-SCHATZ™ Balloon Expandable Stent is indicated for palliation of malignant neoplasms in the biliary tree.

Technological characteristics:

The Long Medium PALMAZ-SCHATZ™ Balloon-Expandable Stents are substantially equivalent in design, function and intended use to the currently marketed PALMAZ™ and PALMAZ-SCHATZ™ Biliary Stents and to the Schneider Wallstent® Biliary Endoprosthesis.

The subject and predicate devices are constructed of surgical grade stainless steel which is a known biocompatible implant material. The subject and predicate devices all have an open mesh design which is

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intended for palliation of malignant neoplasms in the biliary tree. Both the currently marketed and the modified Cordis stents are constructed from stainless steel tubing. The Wallstent® stents are constructed of braided wire.

The subject device and the currently marketed Cordis biliary stents are balloon-expandable. The Wallstent® stents are self-expanding. All of the devices utilize a catheter to deliver the stent. The range of lengths and diameters of the subject and predicate devices are comparable and are intended to meet clinical need.

Diameter: 6-10mm for the subject devices, 4-12mm for the currently marketed Cordis Stents and predetermined 8-10mm for the Wallstent®.

Lengths: 42mm, 56mm and 78mm for the subject device, 10-39mm for the currently marketed Cordis Stents and 15mm to 150mm for the Wallstent® device.

Nonclinical performance:

The differences between the subject and predicate devices are minor and are not relevant to the ability of the subject devices to palliate malignant neoplasms in the biliary tree. The descriptive characteristics are precise enough to demonstrate equivalence. However, qualification testing was performed to confirm the acceptable performance and properties of the subject devices. The following parameters were studied:

Inflation time: Samples were fully expanded to the nominal diameter within the allotted time period.

Balloon burst: Mounted stents did not modify the catheters' labeled maximum burst pressure.

Crossing profile: A 7F sheath is required for 6mm diameter balloons with mounted stents and an 8F sheath is required for 8mm and 10mm diameter balloons with mounted stents.

Distension: All stents reached their nominal diameter within the recommended pressure.

Deflation time/deflatability: All balloons with mounted stents deflated within the allotted time period. The

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presence of the stent did not cause any interference with balloon deflatability.

Stent retention: All samples met or exceeded our internal criteria for stent retention.

Recoil and Length: The stent remains within its nominal diameter after recoil. Lengths were measured to determine stent length at each expanded diameter (for labeling purposes).

Radial Force: The stent will not collapse within the clinically relevant range.

Percent Open Area: All stent sizes have an open area of 80-90% in their expanded diameter range.

MRI Compatibility: The subject devices were found to be MRI compatible.

Fatigue/Corrosion: No cracks or other metallurgical defects resulted from fatigue testing.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Joan Martin
Manager, Regulatory Affairs
Cordis Corporation,
a Johnson & Johnson Company
40 Technology Drive
Warren, New Jersey 07059

Re: K964688
Long Medium PALMAZ-SCHATZ™ Balloon
Expandable Stent
Dated: March 31, 1997
Received: April 1, 1997
Regulatory class: II
21 CFR §876.5010/Product code: 78 FGE

Dear Ms. Martin:

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 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. 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.

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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

If you desire specific advice for your device on our labeling regulation (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/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K964688

Device Name: Long Medium PALMAZ-SCHATZ^{†m}Balloon Expandable Stent

Indications For Use:

The Long Medium PALMAZ-SCHATZ^{†m} Balloon Expandable Stents are indicated for palliation of malignant neoplasms in the biliary tree.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R. Nathan
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K964688

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____