

Cordis Nitinol Stent & Delivery System
Cordis, a Johnson & Johnson Company

510(k) Premarket Notification

510(k) SUMMARY

Submitter's name: Cordis Corporation, a Johnson & Johnson Company
14201 NW 60th Avenue
Miami Lakes, Florida 33014

Contact person: Joan Martin
Manager, Endovascular Regulatory Affairs
(908) 412-7250

Date prepared: March 2, 1998

Trade name: To be determined

Common name: Biliary Stent and Delivery System

Classification name: §876.5010 Biliary Catheter and Accessories

Predicate devices: Wallstent® Biliary Endoprosthesis with Unistep™ Delivery System
Symphony™ Nitinol Stent Transhepatic Biliary System
Bard® Memotherm® Nitinol Stent Transhepatic Biliary Endoprosthesis
PALMAZ™ Balloon-Expandable Stent
PALMAZ™ & PALMAZ-SCHATZ™ Balloon-Expandable Stent and Stent Delivery Systems
Long Medium PALMAZ-SCHATZ™ Balloon-Expandable Stent

Device Description - The subject device is a system consisting of a self-expanding, open mesh, nitinol stent preloaded onto a sheathed delivery catheter. The delivery system is designed to deliver the stent to the stricture site via transhepatic access. Once positioned at the stricture site, the sheath is withdrawn and the stent is released. Upon release, the stent expands and conforms to the inner lumen of the biliary duct. The stent is designed to maintain patency of biliary ducts which have been obstructed by malignant neoplasms.

Labeled Indication: The Cordis Nitinol Stent and Delivery System is intended for palliation of malignant neoplasms in the biliary tree.

Technological Characteristics: The Cordis Nitinol Stent and Delivery System is substantially equivalent in design, function and intended use to currently marketed biliary stents. The subject and predicate stents have a tubular, open mesh design intended for palliation of malignant neoplasms in the biliary tree. The subject stent is self-expandable. The predicate stents are self-expandable or balloon expandable. Both stent types have been shown to be safe and effective. The subject and predicate stents

510(k) Summary (continued)

and delivery systems are constructed of biocompatible materials. The subject and predicate stents are delivered percutaneously via a delivery system. The subject delivery system is a sheathed delivery system. The predicate delivery systems are either sheathed delivery systems or balloon delivery systems. Both system types have been shown to be safe and effective.

The range of lengths and diameters of the subject and predicate stents are comparable and are intended to meet clinical need.

Nonclinical performance: The differences between the subject and predicate devices are minor and are not relevant to the ability of the subject device to palliate malignant neoplasms in the biliary tree. The descriptive characteristics are precise enough to demonstrate equivalence. Preclinical testing was conducted which confirmed the safe and effective performance and biocompatibility of the subject device. Comparative testing was also conducted which confirmed substantial equivalence of the subject and predicate devices.

Conclusion: The Cordis Nitinol Stent and Delivery System is substantially equivalent to currently marketed predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 1998

Ms. Joan Martin
Manager, Regulatory Affairs
Cordis Corporation
P.O. Box 4917
Warren, New Jersey 07059

Re: K980823
Cordis Nitinol Stent and Delivery System for use in biliary ducts
Regulatory Class: II
21 CFR §876.5010
Product Code: 78 FGE
Dated: October 28, 1998
Received: October 29, 1998

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 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.

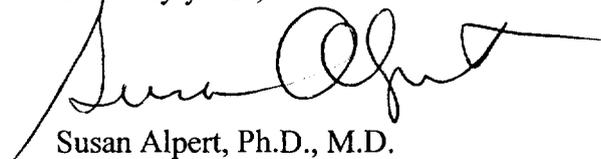
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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



Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): To be Assigned

Device Name: Cordis Nitinol Stent and Delivery System

Indications for Use:

The Cordis Nitinol Stent and Delivery System is intended for palliation of malignant neoplasms in the biliary tree.

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

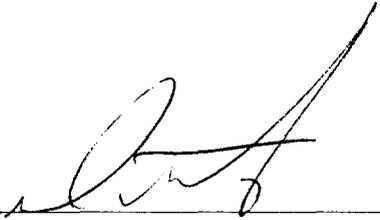
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use

(Optional Format 1/2/96)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number: K980823 / S⁰⁰²