K993646 - Page 1/2

NOV 28 1999

Attachment 4

Summary of Safety and Effectiveness

General Provisions

The name of the device is:

Proprietary Name	Common or Usual Name
Cordis S.M.A.R.T.™ .018" Nitinol Stent Transhepatic Biliary System	Biliary Stent

Name of Predicate Devices

The device is substantially equivalent to:

- Cordis S.M.A.R.T.™ Nitinol Stent Transhepatic Biliary System

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 S.M.A.R.T.™ .018" Nitinol Stent Transhepatic Biliary System** is intended for use in the palliation of malignant neoplasms in the biliary tree.

Device Description

The **Cordis S.M.A.R.T.™ .018" Nitinol Stent Transhepatic Biliary System** 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 Once positioned at the stricture site, the sheath is withdrawn and the stent is released.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.

Biocompatibility

All materials used in the **Cordis S.M.A.R.T.™ .018" Nitinol Stent Transhepatic Biliary System** are biocompatible.

Continued on next page

Summary of Substantial Equivalence

The **Cordis S.M.A.R.T.™ .018" Nitinol Stent Transhepatic Biliary System** is 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

NOV 28 1999

Ms. Elena S. Jugo, R.A.C.
Manager, Regulatory Affairs
Cordis Corporation
P.O. Box 025700
Miami, FL 33102-5700

Re: K993646
Cordis S.M.A.R.T.™ .018" Nitinol Stent
Transhepatic Biliary System
Regulatory Class: II
21 CFR 876.5010
Product Code: 78 FGE
Dated: October 28, 1999
Received: October 29, 1999

Dear Ms. Jugo:

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,

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): K993646

Device Name: Cordis S.M.A.R.T.™ .018" Nitinol Stent Transhepatic Biliary System

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

The Cordis S.M.A.R.T.™ .018" Nitinol Stent Transhepatic Biliary System is intended for use in the palliation of malignant neoplasms in the biliary tree.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993646

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