

**510(k) Summary of Safety and Effectiveness****General Provisions**

The name of the device is:

Proprietary Name	Common or Usual Name
<b>S.M.A.R.T.™ Nitinol Stent Endoscopic Biliary System</b>	Biliary Stent

**Name of Predicate Devices**

The device is substantially equivalent to:

- Cordis S.M.A.R.T.™ Nitinol Stent Endoscopic Biliary System (510(k) # K003365 – November 22, 2000) - Cordis Corporation.
- Cordis S.M.A.R.T.™ Control Nitinol Stent Transhepatic Biliary System (510(k) # K021898 – August 14, 2002) - Cordis Corporation
- SMART Nitinol stent Transhepatic Biliary System (Enhanced Radiopacity) (510(k) # K001843 – July 20, 2000) - Cordis Corporation

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

**Device Description**

The device description of the proposed **S.M.A.R.T.™ Nitinol Stent Endoscopic Biliary System** is as follows.

- 7 French stent delivery system profile;
- Stent material – Nickel Titanium alloy and tantalum micromarkers;
- Expanded stent diameters, 8, 9, and 10 mm;
- Stent lengths 40, 60, and 80 mm;
- Stent delivery system usable length 190 cm; and
- Guidewire lumen 0.035”.

**Biocompatibility**

All materials used in the **S.M.A.R.T.™ Nitinol Stent Endoscopic Biliary System** are biocompatible.

**Summary of  
Substantial  
Equivalence**

The **S.M.A.R.T.<sup>TM</sup> Nitinol Stent Endoscopic Biliary System** is substantially equivalent to the predicate devices. The equivalence was confirmed through pre-clinical testing.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 1 0 2003

Mr. Sam Mirza  
Manager Regulatory Affairs  
Cordis Corporation  
14201 N.W. 60<sup>th</sup> Avenue  
MIAMI LAKES FL 33014

Re: K030409

Trade/Device Name: S.M.A.R.T.<sup>TM</sup> Nitinol Stent Endoscopic Biliary System  
Regulation Number: 21 CFR §876.5010  
Regulation Name: Biliary catheter and accessories  
Regulatory Class: II  
Product Code: 78 FGE  
Dated: February 6, 2003  
Received: February 7, 2003

Dear Mr. Mirza:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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 (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.

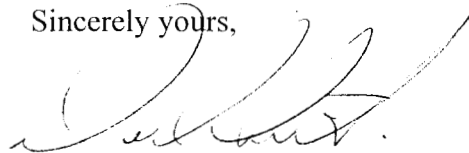
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

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), please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,



Daniel G. Schultz, M.D.  
Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K030409

Device Name: Cordis S.M.A.R.T.™ Nitinol Stent Endoscopic Biliary System

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

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

Perscription Use  OR Over-the-Counter Use   
(Per 21 CFR 801.109)

David R. Byrum  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K030409