510(k) Summary

AUG - 4 2006

Name:	Cook Ireland
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Contact Person:	Emmett Devereux, Quality & RegulatoryManager Sinead Burke, Regulatory Affairs Specialist
Date:	July 28, 2006
Trade Name:	Marathon Stent with Fusion Technology
Common Name:	Stent Introducer with Biliary Stent
Classification Name:	Catheter, Biliary, Diagnostic (21 CFR 876.5010 Product Code FGE)
Legally Marketed Devices:	Olympus PBD Stents (K933200) Wilson-Cook Zimmon Biliary Stent Set (K851962/A) Wilson-Cook OASIS Biliary Stent Introduction System (K040151)
Description of the device:	The Marathon Stent with Fusion Technology is designed to place its preloaded biliary stent to drain obstructed biliary ducts and reduce duodenal content reflux. A soft sock is attached to the proximal end of a traditional biliary stent that reduces duodenal content reflux without compromising antegrade flow. The stent is 10 Fr and will be offered in variable lengths of 5, 7, 9 and 12 cm between the flaps.

Intended Use:	This device is intended for endoscopic placement of a preloaded biliary stent to drain obstructed biliary ducts and reduce duodenal content reflux. This device is supplied sterile and intended for single use only.
Comparison of Characteristics:	We believe the proposed device to be substantially equivalent to currently marketed predicate devices as cleared by K933200, K851962/A and K040151, in terms of intended use, indications for use, performance characteristics, anatomical sites and biocompatibility.
Performance Data:	Non-clinical testing was carried out on the stent to determine the equivalence of the Marathon stent with Fusion Technology to the predicate devices and to verify the safety and effectiveness of the stent. The following is a summary of the testing carried out: verification of Endoscope and wire guide compatibility, validation of stent deployment, sock to stent Security, antegrade flow tests (with simulated bile), retrograde flow tests. Clinical data in support of the claim of substantial equivalence and the intended use of the Marathon stent with Fusion Technology has been collected and presented within this submission. This prospective, randomized clinical study showed that the Marathon Stent with Fusion Technology was as effective as a standard plastic stent, and no new or increased risks related to safety and effectiveness were likely to be raised when compared to risks experienced with similar marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG - 4 2006

Ms. Sinead Burke
Regulatory Affairs Specialist
Cook Ireland Ltd.
O'Halloran Road
National Technology Park
Limerick
IRELAND

Re: K060624
Trade/Device Name: Marathon Stent with Fusion Technology
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: July 12, 2006
Received: July 17, 2006

Dear Ms. Burke:

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) that do not require approval of a premarket approval application (PMA). 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 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K060624

Device Name: Marathon Stent with Fusion Technology

Indications for Use:

This device is intended for endoscopic placement of a preloaded biliary stent to drain obstructed biliary ducts and reduce duodenal content reflux. This device is supplied sterile and intended for single use only.

Prescription Use (Part 21 CFR 801 Subpart D) ✓ ~~AND~~/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lehmann

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060624