AUG 2 3 2005

K051785

510(k) Summary of Safety and Effectiveness Information

Submitted By:

Karen Bradburn, RAC
Senior Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way, PO Box 489
Bloomington, IN 47402
812-339-2235
August 16, 2005

Device:

Trade Name: Formula 418 Biliary Stent
Proposed Classification: Biliary Catheter and Accessories

Indications for Use

Indicated for use in palliation of malignant neoplasms in the biliary tree.

Predicate Devices:

The Formula 418 Biliary Stent is similar in terms of intended use, principles of operation, materials of construction and technological characteristics to predicate devices reviewed as devices for palliation of malignant neoplasms in the biliary tree.

Device Description:

The Formula 418 Biliary Stent is a balloon-expandable, stainless steel stent which is premounted on the delivery system. The stent will be available in diameters of 3, 4, 5, 6, 7, and 8 mm and lengths of 12, 16, 20, 24 and 30 mm. This device will be supplied sterile and is intended for one-time use.

Substantial Equivalence:

The Formula 418 Biliary Stent is similar to many devices in commercial distribution for palliation of malignant neoplasms in the Biliary tree. These devices include the Bridge FX (Bridge Assurant) Stent Delivery System (D.C. #K011817) stent, the Palmaz Genesis Transhepatic Biliary Stent (D.C. #K021345) and the Lifestent LP SDS Biliary Endoprosthesis (D.C.#K023248).

The similar indications for use, principles of operation, technological characteristics and performance testing results of the Formula 418 Biliary Stent

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as compared to the predicate devices support a determination of substantial equivalency.

Test Data:

The Formula 418 Biliary Stent was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

1. Deployment Testing
2. Compression force Testing
3. Expansion Force Testing
4. Dimensional Testing
5. Corrosion Testing
6. Balloon Performance Testing
7. Stent Deformation Testing
8. Tensile Strength Testing
9. Magnetic Resonance Imaging (MRI) Testing
10. Shelf Life Testing
11. Biocompatibility Testing

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as a biliary stent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2005

Ms. Karen Bradburn, RAC
Senior Regulatory Affairs Specialist
Cook Incorporated
P.O. Box 489
BLOOMINGTON IN 47402-0489

Re: K051785
Trade/Device Name: Cook® Formula™ 418™ Biliary Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: August 5, 2005
Received: August 8, 2005

Dear Ms. Bradburn:

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.

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.

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.

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.

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 (240) 276-0115. 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,

Donna-Bea Tillman, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051785

Device Name: Cook® Formula™ 418™ Biliary Stent System

Indications For Use:

The Cook® Formula™ 418™ Biliary Stent is indicated for use in palliation of malignant neoplasms in the biliary tree.

Prescription Use ___X____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051785