NOV 1 6 2001

K010601

**510K SUMMARY**

**Submitted By:** Lisa Hopkins
Regulatory Affairs Coordinator
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, In 47402
(812) 339-2235

**Device:** Trade Name: Fanelli Biliary Stent
Proposed Classification Name: Biliary Catheter and Accessories
21 CFR Part 876.5010, BTO

**Predicate Devices or Legally Marketed Devices:** Ring Biliary Stent — Marketed & Distributed by COOK INCORPORATED

**Device Description**

The Fanelli Biliary Stent consists of several components: 150 cm Hybrid wire guide, NRT guiding catheter, PEEK pushing catheter, NRT introducer sheath, and polyethylene biliary stent. The guiding catheter goes through the lumen of the pushing catheter and the two are connected by Luer lock. The pushing catheter and guiding catheter is then placed through the lumen of the sheath introducer. The stent is pre-loaded into the introducer sheath. This stent is available in 7.0 French outer diameter and lengths of 4, 7 and 10 cm.

The Fanelli Biliary Stent is similar to many devices in commercial distribution for internal biliary drainage. It is identical to the currently marketed Ring Biliary Stent in overall configuration, indications for use and technological characteristics.

**Indications for Use**

The Fanelli Biliary Stent is used for internal biliary drainage. It is provided sterile in peel-open packages and is intended for one-time use.

**Substantial Equivalence**

Prior to enactment of the Medical Device Amendments of 1976, Cook® marketed biliary stent sets. The Ring Biliary Stent Set is a preamendments device. This stent is made of Radiopaque TFE material. It is indicated to be used for internal biliary drainage. The primary difference between this device and the subject of this submission is the material of the stent.

The predicate device is available in a convenience set that includes appropriately sized components. The set for the Fanelli Biliary Stent will include: pushing catheter, guiding catheter, introducer sheath and wire guide. Specific size comparisons between the subject of this submission and the predicate device are listed in the comparison table which follows.

**Test Data**

Testing conducted on the Fanelli Biliary Stent includes:

- Biocompatibility Testing
- Performance 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

NOV 1 6 2001

Ms. Lisa Hopkins
Regulatory Affairs Coordinator
Cook® Incorporated
P.O. Box 489
BLOOMINGTON IN 47402-0489

Re: K010601
Trade/Device Name: Fanelli Biliary Stent
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: August 17, 2001
Received: August 20, 2001

Dear Ms. Hopkins:

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 (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.

This letter will allow you to begin marketing your device as described in your 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:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

510(k) Number (if known): K010601 NOV 1 6 2001

Device Name Fanelli Biliary Stent

Indications for Use:

The Fanelli Biliary Stent is used for internal biliary drainage.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K010601