K101095
pg 1 of 2

COOK ENDOSCOPY
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JUL 19 2010

FDA CDRH DMC

APR 20 2010

Received

510(k) Summary

Name:	Cook Endoscopy
Address:	4900 Bethania Station Road Winston-Salem, North Carolina 27105
Phone:	(336)744-0157
Fax:	(336)201-5994
Contact:	Scottie Fariole, Global Regulatory Affairs Specialist
Date:	April 8, 2010
Trade Name:	Direct Peroral Cholangioscopy Balloon
Common Name:	Balloon Catheter
Classification Name:	Mini Endoscope, Gastroenterology-Urology (21 CFR 876.1500, Product Code ODF) Catheter, biliary, surgical (21 CFR 876.5010, Product Code GCA)
Legally Marketed Devices:	SpyScope Access and Delivery Catheter (K090170) Fusion Quattro Extraction Balloon XL (K063677)
Description of the Device:	The Direct Peroral Cholangioscopy Balloon is a sterile, single use device used to gain access for direct peroral cholangioscopy. The device is placed through a duodenoscope with a minimum accessory of 2.0 mm. The latex balloon is then anchored within the pancreaticobiliary system to guide forward viewing endoscopes for diagnostic and therapeutic applications. It can also remove biliary stones.
Intended Use:	This device is intended to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts. Also, used for endoscopic removal of biliary stones.

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Technological Characteristics:	The Direct Peroral Cholangioscopy Balloon has similar technological characteristics to the to the Fusion Quattro Extraction Balloon XL (K063677) in terms of general design, materials and operation but differs in terms of dimensions, number of lumens, modifications to the proximal and distal ends of the device and extent of expansion.
Performance Data:	Performance testing consisting of non-clinical bench testing demonstrates that the Direct Peroral Cholangioscopy Balloon met the performance requirements of the expanded intended use. The device will be substantially equivalent to currently cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6(
Silver Spring, MD 20993-0002

Mr. Scottie Fariole
Global Regulatory Affairs Specialist
Wilson-Cook Medical, Inc
4900 Bethania Station Road
WINSTON-SALEM NC 27105

JUL 19 2010

Re: K101095
Trade/Device Name: Direct Peroral Cholangioscopy Balloon
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: Class II
Product Code: FGE
Dated: April 8, 2010
Received: April 20, 2010

Dear Mr. Fariole:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101095

Device Name: Direct Peroral Cholangioscopy Balloon

Indications for Use:

This device is intended to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts. Also, used for endoscopic removal of biliary stones.

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)

Colleen M. Pollard

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K101095