K072521

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510(k) SUMMARY

Submitted by:

Cindy Foote
Regulatory Affairs Specialist
Cook Urological, Incorporated
1100 West Morgan Street
Spencer, IN 47460
812-829-4891 x7281
August 31, 2007

NOV 20 2007

Device:

Trade Name: Cook® Fiber Optic Bundle and Flexor® Deflecting Access Sheath (Final Trade Name is not yet determined)

Proposed Classification: Endoscope, Fiber Optic
Laparoscope, General and Plastic Surgery
Sheath, for Endoscope

21 CFR Part 876.1500

Product Codes and Class: 78GDB, Class II
78GCJ, Class II
78FED, Class II

Predicate Devices:

The Cook® Fiber Optic Bundle and Flexor® Deflecting Access Sheath are similar with respect to indications for use and technology to existing predicate devices in commercial distribution. Specifically, The Cook® Fiber Optic Bundle is similar to the Karl Storz Fiberscope (K925128/B) manufactured by Karl Storz Endoscope and the Flexible Fiber Optic Bundle(K922826) manufactured by Optimed Technologies, Incorporated. The Deflecting Flexor Access Sheath is similar to the Flexor DL Ureteral Access Sheath (K043418) manufactured by Cook Urological, Incorporated and the Forte' Plus Deflecting Renal Access Sheath (K030642) manufactured by Applied Medical.

Device Description:

The Cook® Fiber Optic Bundle is a small diameter fiber optic consisting of inner illuminating fibers and an outer imaging fiber bundle contained in a plastic sleeve. At one end of the imaging bundle is a distal lens and at the other end a fixed eyepiece. The distal lens system focuses an image of the target area under observation onto the tip of the optical imaging fiber bundle. The image is then transmitted to an adjustable focus eyepiece or video adapter at the proximal end of the fiber optic. The eyepiece or video adapter may be connected to a standard video camera to allow the image to be viewed on a video monitor. The light transmitting optical fibers used for illumination have a separate adapter which couples to the external light source. The Fiber Optic Bundle is 2.8

French and available in lengths ranging of 115 and 150cm. The fiber optics are supplied sterile and are intended for up to 10 uses and may be sterilized or disinfected by liquid immersion.

The Flexor® Deflecting Access Sheath is a single use sterile dual lumen access sheath that is used to provide access as well as protection of the Cook® Fiber Optic Bundle and has a second working channel for passage of additional instrumentation. The Flexor® Deflecting Access Sheath consists of a tapered dilator and a dual lumen sheath. The sheath is hydrophilically coated, which is activated when wetted. The sheath is attached to a handle assembly which when manipulated allows the tip of the sheath to deflect. When assembled, the Fiber Optic Bundle and sheath act in a manner similar to a flexible endoscope. Because the sheath is deflectable and the Fiber Optic Bundle is flexible, the user is able to position the Fiber Optic Bundle to the desired site in the appropriate body cavity or organ. The sheath has two lumens which allows one lumen to be an access channel for Endoscopic instrumentation and the second lumen to be used as an access port for the fiber optic bundle. The Flexor Deflecting Ureteral Access Sheaths will be available in 45 and 75 centimeter lengths. The Flexor® Deflecting Ureteral Access Sheath will be available in 45 and 75cm lengths. The outside diameter is 15 French. The large lumen's inside diameter is 8.85 French and the inside diameter of the smaller lumen is 3.15 French. When assembled with the Cook® Fiber Optic, the Flexor® Deflecting Access Sheath provides protection for the Cook® Fiber Optic Bundle and deflects up to 180°.

The Cook® Fiber Optic Bundle and Flexor® Deflecting Access Sheath will be sold sterile as sets as well as sterile single order items.

Substantial Equivalence:
The Cook® Fiber Optic Bundle and Flexor® Deflecting Access Sheath are comparable with respect to intended use to the available predicate device description and meet the requirements for 510(k) substantial equivalence.

Test Data:
Biocompatibility and bench performance testing was performed to demonstrate the safety and performance of the Cook® Fiber Optic bundle and the Cook® Fiber Optic Bundle and Flexor® Deflecting Access Sheath when used together. Testing was performed by Cook Urological, Incorporated and an independent laboratory in accordance with recognized standards. All test results were acceptable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2007

Ms. Cindy Foote
Regulatory Affairs Specialist
COOK UROLOGICAL INC.
1100 West Morgan Street
SPENCER IN 47460

Re: K072521
Trade/Device Name: Cook® Fiber Optic Bundle and Flexor® Deflecting Access Sheath
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Codes: FED, FFS, FAJ, FGA, GCJ and FGB
Dated: September 6, 2007
Received: September 7, 2007

Dear Ms. Foote:

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

Indications for Use

510(k) Number (if known): K072521

Device Name: Cook® Fiber Optic Bundle and Flexor® Deflecting Access Sheath

Indications for Use: The Cook® Fiber Optic Bundle and Flexor® Deflecting Access Sheath are intended for use during cystoscopic, nephroscopic, laparoscopic and ureteroscopic procedures. The Cook® Fiber Optic Bundle is intended for direct visualization of body cavities or organs. The Flexor® Deflecting Access Sheath is used to provide access as well as protection for the Cook® Fiber Optic Bundle and has a second working channel for passage of additional instrumentation.

Prescription Use?___X_____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072521