K043418

COOK®

MAR 3 1 2005

Cook Urological
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Spencer, IN 47460 USA
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I. 510(k) SUMMARY

Submitted By:
Cindy Rumple
Cook Urological
1100 West Morgan Street
Spencer, Indiana 47460
(812) 829-4891
December 8, 2004

Device

Trade Name:	Cook® Pediatric Flexor Ureteral Access Sheath
Proposed Classification Name:	Sheath, for Endoscope, Ureteral Dilator Class II 78 FED 876.1500

Predicate Devices:
The Cook® Pediatric Flexor Ureteral Access Sheath is similar with respect to indications for use and technology to exist predicate devices in commercial distribution. Specifically, the Cook® Pediatric Flexor Ureteral Access Sheath is similar to the AQ Hydrophilic Dilator (K961904) manufactured by Cook Urological, Incorporated, the Bard® Aqua Guide Ureteral Conduit (K030438) manufactured by C.R. Bard, Incorporated, the Bard® Aqua Guide Ureteral Access Sheath (K033778) manufactured by C.R. Bard, Incorporated, the Ureteral Access Sheath Set (K993650) manufactured by Applied Medical Resources Corporation, the Ureteral Access Sheath Set (K990775) manufactured by Applied Medical Resources Corporation, and the Ureteral Access Sheath Set II (K030956) manufactured by Boston Scientific Corporation (Microvasive).

Device Description:
The Cook® Pediatric Flexor Ureteral Access Sheath is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract. The Cook® Pediatric Flexor Ureteral Access Sheath is intended for Pediatric Use in patients two years of age and older.

The Cook® Pediatric Flexor Ureteral Access Sheath is a single use sterile device that is offered as a single or dual lumen device. The Cook® Pediatric Flexor Ureteral Access Sheath will be offered in a 9.5 French inside diameter 13 centimeter length or 12 French inside diameter 13 centimeter length single lumen version. The Cook® Pediatric Flexor Ureteral Access Sheath will also be offered in a 9.5 French inside diameter 13 centimeter length or 12 French inside diameter 13

centimeter length dual lumen version. The main lumen of the 9.5 French dual lumen version is 9.5 French inside diameter and the main lumen of the 12 French dual lumen version is 12 French inside diameter. The secondary lumen on both sizes is 3 French inside diameter. Both versions and sizes of the device will be AQ Hydrophilically coated which, when activated, allows easier insertion and removal of the sheath.

The construction materials of the Cook® Pediatric Flexor Ureteral Access Sheath are all well known in the medical field. Biocompatibility testing has shown the materials to meet the test requirements. Bench top testing, coefficient of friction testing, irrigation flow study, buckling pressure test, kink resistance testing, risk analysis, complaints verses sales data, clinical feedback, and published articles support our claim that the device is as safe and effective in the pediatric population as in adult use.

Substantial Equivalence:
The device will be manufactured according to specified process controls and a Quality Assurance Program. The device will undergo packaging and sterilization procedures similar to devices currently marketed and distributed by Cook Urological, Incorporated. Being similar with respect to indications for use, materials, and physical construction to predicate devices, this device meets the requirements for section 510 (K) substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1 2005

Ms. Cindy Rumple
Regulatory Affairs Technical Writer
Cook® Urological
1100 W. Morgan Street
SPENCER IN 47460

Re: K043418
Trade/Device Name: Cook® Pediatric Flexor Ureteral Access Sheath
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: February 23, 2005
Received: March 1, 2005

Dear Ms. Rumple:

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.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" (21 CFR 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,

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

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K043418

Device Name: Cook® Pediatric Flexor Ureteral Access Sheath

Indications for Use: Used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract. The Cook® Pediatric Flexor Ureteral Access Sheath is intended for Pediatric Use in patients two years of age and older.

Prescription Use ____X_____ OR Over the Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043418