K060673

MAR 2 9 2006

510(k) SUMMARY

510(k) NUMBER: PENDING

SUBMITTED BY: Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688
(949) 713-8327

CONTACT PERSON: Cheryl Blake
V.P. Regulatory Affairs and Quality Systems

DATE OF PREPARATION: March 9, 2006

NAME OF DEVICE: Pediatric Ureteral Stents

CLASSIFICATION NAME: Ureteral Stent, 21 CFR 876.4620.

TRADE NAME: Not Determined

SUMMARY STATEMENT:

The Applied Medical Pediatric Ureteral Stent is indicated to relieve obstruction from a variety of benign and malignant conditions in the ureter such as presence of stones and/or stone fragments, or other ureteral obstructions such as those associated with ureteral stricture, carcinoma of abdominal organs, retroperitoneal fibrosis, or in association with extracorporeal shockwave lithotripsy, (ESWL) in patients 2 years of age and older. The stent is also used after ureteroscopy to prevent obstruction due to edema or following accidental, or planned ureteral perforation/incision to provide drainage and a scaffold for the healing ureter. In the latter circumstance it is usually used in combination with a urethral drainage catheter (e.g. Foley Catheter). The stent may be placed using retrograde endoscopic and/or fluoroscopic techniques, or percutaneously using standard radiographic technique, or at open surgery.

The stent is also indicated for use as a temporary indwelling ureteral catheter to assist in urine drainage through obstructed or strictured ureters.

The Applied Medical Pediatric Ureteral Stent is substanually equvalant to its predicates devices the Cook Sof-Flex Pediatric Double Pigtail Stent and the Applied Medical Ureteral Stent in design methodology, principle of operation and clinical utility. The device introduces no new safety or effectiveness issues when used as instructed.

Performance tests were selected based on the FDA document titled "Guidance for the Content of Premarket Notifications for Ureteral Stents", which advises that the 510(k) submission should include the following data to demonstrate substantial equivalence: Flow rate, Elongation and Tensile Strength, Curl Strength (Coil retention), and Coefficient of Friction. These characteristics were tested in the predicate device (Cook Sof-Flex 3F Pediatric Ureteral Stent) and in the Applied Medical devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2006

Applied Medical Resources Corporation
c/o Mr. Morten Simon Christensen
Staff Engineer & FDA Office Coordinator
Medical Device Services
Underwriters Laboratories, Inc.
455 East Trimble Road
SAN JOSE CA 95131-1230

Re: K060673
Trade/Device Name: Pediatric Ureteral Stent
Regulation Number: 21 CFR §876.4620
Regulation Name: Ureteral stent
Regulatory Class: II
Product Code: FAD
Dated: March 13, 2006
Received: March 14, 2006

Dear Mr. Christensen:

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/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): _____

Device Name: ____Pediatric Ureteral

Stent_____

Indications for Use:

The Applied Medical Pediatric Ureteral Stent is indicated to relieve obstruction from a variety of benign and malignant conditions in the ureter such as presence of stones and/or stone fragments, or other ureteral obstructions such as those associated with ureteral stricture, carcinoma of abdominal organs, retroperitoneal fibrosis, or in association with extracorporeal shockwave lithotripsy, (ESWL) in patients 2 years of age and older. The stent is also used after ureteroscopy to prevent obstruction due to edema or following accidental, or planned ureteral perforation/incision to provide drainage and a scaffold for the healing ureter. In the latter circumstance it is usually used in combination with a urethral drainage catheter (e.g. Foley Catheter). The stent may be placed using retrograde endoscopic and/or fluoroscopic techniques, or percutaneously using standard radiographic technique, or at open surgery.

The stent is also indicated for use as a temporary indwelling ureteral catheter to assist in urine drainage through obstructed or strictured ureters.

Prescription Use ___X___ (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)

David A Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060673

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