K040760

OCT 15 2004

510(k) SUMMARY

510(k) NUMBER:

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 2, 2004

NAME OF DEVICE: Ureteral Stents

CLASSIFICATION NAME: Ureteral Stent, 21 CFR 876.4620.

TRADE NAME: Not Determined

SUMMARY STATEMENT:

The Applied Medical 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). 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 Applied Medical Ureteral Stents are substantially equivalent to predicate devices and introduce no new safety and effectiveness issues when used as instructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2004

Ms. Cheryl A. Blake
Vice President, Regulatory Affairs
and Quality Systems
Applied Medical Resources Corporation
22872 Avenida Empresa
RANCHO SANTA MARGARITA CA 92688

Re: K040760
Trade/Device Name: Applied Medical Ureteral Stent
Regulation Number: 21 CFR §876.4620
Regulation Name: Ureteral stent
Regulatory Class: II
Product Code: 78 FAD
Dated: September 25, 2004
Received: September 30, 2004

Dear Ms. Blake:

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

Indications for Use

510(k) Number (if known): K040760

Device Name: Ureteral Stent

Indications for Use: The Applied Medical 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). 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 AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040760