K991219

JUN 21 1999

510(k) SUMMARY

510(k) NUMBER: PENDING

SUBMITTED BY:

Applied Medical Resources Corporation
26051 Merit Circle, Unit # 103
Laguna Hills, California 92653
(949) 582-6120

CONTACT PERSON:

Anil Bhalani
Director of Regulatory Affairs and Clinical Programs

DATE OF PREPARATION: April 7, 1999

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

JUN 21 1999

Mr. Anil Bhalani
Director of Regulatory Affairs and
Clinical Programs
Applied Medical®Resources
26051 Merit Circle, Building 104
Laguna Hills, CA 92653

Re: K991219
C-Flex Ureteral Stents
Dated: April 9, 1999
Received: April 12, 1999
Regulatory Class: II
21 CFR §876.4620/Procode: 78 FAD

Dear Mr. Bhalani:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applied Medical Resources is providing this separate cover page for the Ureteral Stents "Indications for Use" as required.

510(k) Number: ~~Not assigned~~ K991219

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.

Signature: _____ Title: *Director RA/Clinical Programs* Date: *4-7-99*
ANIL BHALANI

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format -2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991219