MAY 2 3 2003

K030642
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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:	Anil Bhalani Vice President of Regulatory Affairs and Clinical Programs
DATE OF PREPARATION:	February 20, 2003
NAME OF DEVICE:	Deflecting Ureteral Access Sheath
CLASSIFICATION NAME:	Sheath, for Endoscope Endoscope and Accessories, 21 CFR 876.1500
TRADE NAME:	Not Determined
PREDICATE DEVICES:	Forte Ureteral Access Sheath Set (K993650 and K990775) Applied Medical Resources Corporation Rancho Santa Margarita, CA

INTENDED USE: The Deflecting Ureteral Access Sheath is indicated for use in endoscopic urology procedures, facilitates the passage of endoscopes and other instruments through the urinary tract. The dilator may also be used to irrigate and aspirate fluids into the urinary tract and kidney.

DEVICE DESCRIPTION: The Deflecting Ureteral Access Sheath consists of a tapered dilator and a sheath, which are both coated with a hydrophilic coating, which is activated when wet. The tip of the sheath is designed such that it may be deflected in order to position the tip of the sheath to a desired site within the kidney to allow better access to surgical site. The deflecting feature also aids in positioning/maneuvering instruments such as endoscopes positioned inside the sheath.

The Deflecting Ureteral Access Sheath consists of two components, the sheath and the dilator. The sheath consists of an elongated body attached to a lever and handle assembly. Activation of the handle/lever mechanism results in desired deflection of the tip of the sheath. The dilator is assembled into the sheath during placement. The tapered tip of the dilator is designed for easy placement. The Deflecting Ureteral Access Sheath can be placed over a guidewire or by itself. The female luer fitting on the dilator is securely attached to the sheath handle during placement. Devices such as syringes and suction and irrigation equipment with luer port connectors may be

attached to the dilator when irrigation and/or aspiration of the surgical site is desired. The dilator may also be used by itself in similar procedures.

The Deflecting Ureteral Access Sheaths will be made available as disposable, single use, sterile devices in two sizes (35cm and 60 cm).

PERFORMANCE DATA SUMMARY: The performance and functional testing of the Deflecting Ureteral Access Sheath included tests to verify Surface Friction and Hydrophilic Coating Adhesion, Kink Free Test, Tip Deflection Test. The performance and functional testing demonstrates that the Deflecting Ureteral Access Sheath is substantially equivalent to the predicate devices and it introduces 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

MAY 23 2003

Mr. Anil Bhalani
Vice President of Regulatory Affairs
and Clinical Programs
Applied Medical Resources
22872 Avenida Empresa
RANCHO SANTA MARGARITA CA 92688

Re: K030642
Trade/Device Name: Deflecting Ureteral Access Sheath
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FED
Dated: February 20, 2003
Received: February 28, 2003

Dear Mr. Bhalani:

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 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

K030642

INDICATIONS FOR USE

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

510(k) Number: ~~Not assigned~~ K030642

Device Name: Deflecting Ureteral Access Sheath

Indications for Use: The Deflecting Ureteral Access Sheath is indicated for use in endoscopic urology procedures, facilitates the passage of endoscopes and other instruments through the urinary tract. The dilator may also be used to irrigate and aspirate fluids into the urinary tract and kidney.

Signature: _____ Title: *V.P., RA/Clinical Programs* Date: *2-20-03*

(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)

David A. Ferguson
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030642