K993650

DEC 28 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: October 22, 1999

NAME OF DEVICE: Ureteral Access Sheath Set

CLASSIFICATION NAME: Endoscope and Accessories, 21 CFR 876.1500

TRADE NAME: Not Determined

PREDICATE DEVICES:

1. Applied Medical Ureteral Access Sheath Set (K990775)
2. Cook Urological's Peel Away Introducer Sets.
3. Nottingham One-Step Tapered Dilators, Boston Scientific Corporation.

INTENDED USE: The Ureteral Access Sheath Set is indicated for use in endoscopic urology procedures, by facilitating the passage of endoscopes and other instruments through the urinary tract. The Ureteral Access Sheath Set is comprised of two components: a tapered dilator and a sheath; both have a hydrophilic coating.

The Applied Medical Ureteral Access Sheath Set is substantially equivalent to predicate devices and introduces no new safety and effectiveness issues when used as instructed.

DEVICE DESCRIPTION: The Ureteral Access Sheath Set is a single use sterile device, indicated for use in endoscopic urology procedures, to facilitate the passage of endoscopes and other instruments through the urinary tract. It is comprised of two components: a dilator with a tapered tip and a tapered sheath. Both the sheath and the dilator are made from polyurethane. The sheath length varies from 20 cm (shortest) to 60 cm (longest) by model.

A luer fitting made attached to the proximal end of the dilator may be used to introduce contrast during a retrograde pyelogram procedure. The dilators range in length from 25 cm (shortest) to 70 cm (longest). The thru-lumen of the dilator tip is 0.040 - 0.045 inches and it can be used over a guidewire of up to .038 inches diameter.

70 cm (longest). The thru-lumen of the dilator tip is 0.040 - 0.045 inches and it can be used over a guidewire of up to .038 inches diameter.

The sheath and the dilator are coated with a hydrophilic coating, which is activated by wetting the device in saline or sterile water. The hydrophilic feature allows for easier insertion and removal of the ureteral sheath.

The luer fitting on the dilator cannot be pushed through the lumen of the cone shaped handle because of its larger size and therefore acts as a safety feature by preventing the dilator from being over inserted into the sheath.

A latch mechanism is added to the ureteral access sheath set, which locks the dilator in place inside the sheath during insertion of the dilator and sheath in the urological tract.

Two suture loops are attached at the cone of the sheath, which may be used to secure the sheath to the drapes of the patient to retain the sheath in position during surgery. This feature is a convenience to the surgeon who may otherwise have to hold the sheath in position during surgery.

PERFORMANCE DATA SUMMARY: The performance and functional testing of the Ureteral Access Sheath Set includes tests to verify Surface Friction and Hydrophilic Coating Adhesion, Fluid Flow, Handle Pull Strength and Luer Fitting Pull Strength. The performance and functional testing demonstrates that the Ureteral Access Sheath Set 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

DEC 28 1999

Mr. Anil Bhalani
Director of Regulatory Affairs and Clinical Programs
APPLIED MEDICAL RESOURCES
26051 Merit Circle
Bldg. 104
Laguna Hills, CA 92653

Re: K993650
Ureteral Access Sheath Set
Dated: October 29, 1999
Received: October 29, 1999
Regulatory Class: II
21 CFR §876.1500/Procode: 78 FED

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 Access Sheath Set "Indications for Use" as required.

510(k) Number: Not assigned

Device Name: Ureteral Access Sheath Set

Indications for Use: The Ureteral Access Sheath Set is indicated for use in endoscopic urology procedures, by facilitating the passage of endoscopes and other instruments through the urinary tract.

Signature: _____ Title: *Director RA/Clinical Programs* Date: *10-29-99*

(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 K993650