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ACMI

510(k) Summary

Submitted by:	ACMI Corporation 136 Turnpike Road Southborough MA 01772-2104 866 879-0640
Contact Person:	Graham A. L. Baillie
Date Prepared:	June 15, 2005
Proprietary Name:	UroPass® Ureteral Access Sheath
Common Name:	Ureteral Access Sheath
Classification Name:	Urological catheter and accessories
Predicate Device(s):	Snap-N-Peel™ Introducer K981611 Applied Medical Ureteral Access Sheath K993650

Description of the Device:

The UroPass Access Sheath is a single use, sterile (EtO sterilized) disposable product. The sheath is made of layers of polyurethane and PTFE with a stainless steel coil sandwiched in between (the coil provides kink resistance). The sheath has a funnel at the proximal end to ease the insertion of an LDPE dilator. The dilator is equipped with a polypropylene luer connector for injection of irrigation or contrast. The dilator is removable from the sheath by means of a clip fixed to the luer connector. The outside of the sheath has a lubricious coating for ease of insertion into the ureter. For ease of visualization, the dilator and sheath are radiopaque. Two holes (suture loops) are incorporated into the funnel to facilitate attachment to surgical drapes for stabilization of the sheath during surgery.

Intended Use of the Device:

The UroPass Ureteral Access Sheath is intended to be a conduit for the passage of endoscopes and other urological devices for the purpose of performing diagnostic and surgical procedures, such as, nephrostomy, cystoscopy, or ureteroscopy, in the urinary tract.

Technological Characteristics and Substantial Equivalence:

The fundamental technology of the modified device has not changed. The UroPass Ureteral Access Sheath remains a ureteral access sheath that permits direct passage of catheters, endoscopes and other devices through the urinary tract. The UroPass Ureteral Access Sheath is substantially equivalent in design, materials and intended use to previously cleared devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 0 2 2005

Mr. Graham Baillie
Senior Regulatory Specialist
ACMI Corporation
136 Turnpike Road
SOUTHBOROUGH MA 01772-2104

Re: K051593
Trade/Device Name: UroPass® Ureteral Access Sheath
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: KNY
Dated: August 11, 2005
Received: August 16, 2005

Dear Mr. Baillie:

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 STATEMENT

Device Name: UroPass® Ureteral Access Sheath

510(k) Number: K051593

Indications for use:

Intended to be a conduit for the passage of endoscopes and other urological devices for the purpose of performing diagnostic and surgical procedures, such as, nephrostomy, cystoscopy, or ureteroscopy, in the urinary tract.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: __X__ **OR** Over-the-Counter Use: _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051593