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Astra Tech, Inc

DEC 23 2004

510K Summary of Safety and Effectiveness

Astra Tech AB Lofric Hydro-Kit II Single Use Urinary Catheter

1. Sponsor Name
   Astra Tech, Inc.

2. Device Name

Proprietary Name:	Astra Tech AB LoFric® Hydro-Kit II Single Use Urinary Catheter
Common/Usual Name:	Urethral Catheters
Classification Name:	Urethral Catheters and Accessories 72 GBM, Class II – Urology Devices

3. Identification of Legally Marketed Device

   The modified The LoFric® Hydro-Kit II Single Use Urinary Catheter is substantially equivalent in intended use to the LoFric® Single Use Urinary Catheter (K896750).

4. Device Description
   The LoFric® Hydro-Kit II Single Use Urinary Catheter is designed as an intermittent pathway for drainage of the bladder. The device consists of a catheter, coated with a hydrophilic low-friction coating.

   The surface is hydrophilic and when the catheter is immersed in water or physiological saline solution for 30 seconds, it becomes slippery and ready to use. The catheter is provided in a variety of lengths and sizes.

   The catheter is packed within a bag for urine collection. The urine collection bag is used as a wetting container prior to catheterization. Inside the closed urinary bag, a water sachet is placed. By holding the product upright and exerting a light pressure on the folded water sachet, the water will activate the hydrophilic catheter surface.

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5. Intended Use

The LoFric® Hydro-Kit II Single Use Urinary Catheter is intended for intermittent catheterization of the urethra.

6 Comparison of Technological Characteristics

The modified The LoFric® Hydro-Kit II Single Use Urinary Catheter is substantially equivalent in intended use and design to the currently marketed The LoFric® Single Use Urinary Catheter (K896750).

The difference between the LoFric® Hydro-Kit II Single Use Urinary Catheter and the predicate is the packaging concept and addition of accessories as urine collection bag and water sachet. The method of sterilization is changed. This difference does not raise new questions of safety and effectiveness. Laboratory data demonstrates this.

6. Performance Testing

Laboratory testing and biocompatibility testing was conducted to determine device functionality and conformance to design input requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2004

Mr. Niklas Lidskog
President
Astra Tech, Inc.
890 Winter Street, Suite 310
WALTHAM MA 02451

Re: K043241
Trade/Device Name: Astra Tech AB LoFric® Hydro-Kit II Single Use Urinary Catheter
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 GBM
Dated: November 22, 2004
Received: December 1, 2004

Dear Mr. Lidskog:

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 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

510(k) Number (if known): K043241

Device Name: Astra Tech AB LoFric® Hydro-Kit II Single Use Urinary Catheter

Indications For Use: The LoFric® Hydro-Kit II Single Use Urinary Catheter is intended for intermittent catheterization of the urethra.

(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)

David A. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043241