K012374
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AUG 2 3 2001

510K Summary of Safety and Effectiveness

Astra Tech AB Lofric Plus Catheter

1. Sponsor Name

   Astra Tech, INC.
   430 Bedford St.
   Lexington, MA 02173

2. Device Name

Proprietary Name:	Astra Tech AB LoFric® Plus 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® Plus Single Use Urinary Catheter is substantially equivalent in intended use to the LoFric® Single Use Urinary Catheter (K896750).

4. Device Description

   The LoFric® Plus 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 andsizes.

5. Intended Use

   The LoFric® Plus Single Use Urinary Catheter is intended for intermittent catheterization of the urethra.

6 Comparison of Technological Characteristics

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

The only difference between the LoFric® Plus Single Use Urinary Catheter and the predicate is the material and the addition of a 15 cm size length to the product line. These differences do 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

AUG 2 3 2001

Astra Tech AB
% Mr. Bruce R. Manning
New England Biomedical Research, Inc.
96 West Main Street
NORTHBOROUGH MA 01532

Re: K012374
Astra Tech AB LoFric® Plus Single Use Urinary Catheter
(Urological Catheters and Accessories)
Dated: July 25, 2001
Received: July 26, 2001
Regulatory Class: II
21 CFR 876.5130/Procode: 78 GBM

Dear Mr. Manning:

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) 594-4639. 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" (21CFR 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

510(k) Number (if known): K012374

Device Name: Astra Tech AB LoFric® Plus Single Use Urinary Catheter

Indications For Use: The LoFric® Plus 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)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012374