K113424

510(k) Summary

APR 17 2012

Astra Tech AB

LoFric® Single Use Urinary Catheter

April 17, 2012

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Astra Tech AB Aminogatan 1, P.O. Box 14 Mölndal, Sweden SE-431 21 Telephone: +46 31 776 30 00 Fax: +46 31 776 30 10
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	LoFric® Single Use Urinary Catheter
Classification Name:	Urological catheter and accessories
Classification Regulations:	21 CFR Part 876.5130, Class II
Product Code:	EZD
Classification Panel:	Gastroenterology and Urology Devices Panel
Reviewing Branch:	Urology and Lithotripsy Devices Branch

INTENDED USE

LoFric® Single Use Urinary Catheter is intended for intermittent urinary catheterization.

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DEVICE DESCRIPTION

The LoFric® Single Use Urinary Catheter is designed as an intermittent pathway for drainage of the bladder. This device is a single-use disposable unit and is packaged in a thermoformed tray with a heat sealed paper lid. The catheter is available in a variety of lengths and configurations to accommodate individual anatomy of both male and female users. Both Nelaton (straight tip) and Tiemann (curved tip) designs are available.

EQUIVALENCE TO MARKETED DEVICE

Astra Tech AB submits information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the LoFric® Single Use Urinary Catheter is substantially equivalent in indications and design principles to the following legally marketed predicate device, which has been determined by FDA to be substantially equivalent to a legally marketed predicate device:

Astra Tech LoFric® Single Use Urinary Catheter – K896750

The subject device and the predicate device both have the same intended use, which is for intermittent urinary catheterization. Both are single-use plastic catheters coated with polyvinyl pyrrolidone. Both are made using the same basic manufacturing technology, and both have the same performance characteristics. Performance testing and biocompatibility testing were submitted to address efficacy and safety of the device and to show substantial equivalence to the predicate device.

Overall, LoFric® Single Use Urinary Catheter has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Astra Tech AB
% Mr. Floyd G. Larson
President
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11234 El Camino Real, Suite 200
SAN DIEGO CA 92130

APR 17 2012

Re: K113424
Trade/Device Name: LoFric® Single Use Urinary Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: March 30, 2012
Received: April 2, 2012

Dear Mr. Larson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K113424

Device Name: LoFric® Single Use Urinary Catheter

Indications for Use:

LoFric® Single Use Urinary Catheter is intended for intermittent urinary catheterization.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastrorenal, and Urological Devices
510(k) Number K113424