510(k) Summary

OCT 31 2012

Astra Tech

LoFric® Primo™ and LoFric® Hydro-Kit™

July 13, 2012

ADMINISTRATIVE INFORMATION

Manufacturer Name	Astra Tech Aminogatan 1, P. O. Box 14 Mölndal, Sweden SE-431 21 Telephone: +46 31 776 30 00 Fax: +46 31 776 30 10
Official Contact	Christina Lewing Head of Regulatory Affairs
Representative/Consultant	Allison C. Komiyama, Ph.D. Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: akomiyama@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	LoFric® Primo™ and LoFric® Hydro-Kit™
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® Primo™ and LoFric® Hydro-Kit™ are intended for intermittent urinary catheterization.

DEVICE DESCRIPTION

The LoFric® Primo™ and LoFric® Hydro-Kit™ are single-use catheters designed as intermittent pathways for drainage of the bladder. The catheters are 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. Each catheter is packaged along with a water packet that is to be broken immediately before use in order to soak the tubing.

EQUIVALENCE TO MARKETED DEVICE

Astra Tech submits information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the LoFric® Primo™ and LoFric® Hydro-Kit™ are substantially equivalent in indications and design principles to the following legally marketed predicate devices:

Astra Tech AB, LoFric® Single Use Urinary Catheter – K113424
Astra Tech, Inc., Astra Tech AB LoFric® Hydro-Kit II Single Use Urinary Catheter – K043241
Astra Tech, Inc., Astra Tech AB LoFric® Primo™ Single Use Urinary Catheter – K050874

The subject devices and the predicate device have the same intended use, which is for intermittent urinary catheterization. All are single-use plastic catheters coated with polyvinyl pyrrolidone. They are made using the same basic manufacturing technology, and all have similar 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 devices. Any differences in the technological characteristics between the subject and predicate devices do not raise new issues of safety or efficacy.

Non-clinical testing data that was submitted, referenced, or relied upon to demonstrate substantial equivalence included: dimensional analysis, biocompatibility testing and modified performance testing according to ASTM F623.

The data included in this submission demonstrates substantial equivalence to the predicate devices listed above.

Overall, LoFric® Primo™ and LoFric® Hydro-Kit™ 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 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 Center – WO66-G609
Silver Spring, MD 20993-002

OCT 31 2012

Astra Tech, Inc.
% Allison C. Komiyama, Ph.D.
Regulatory Specialist
PaxMed International, LLC
11234 El Camino Real, Suite 200
SAN DIEGO CA 92130

Re: K122078
Trade/Device Name: LoFric® Primo™ and Lofric® Hydro-Kit™
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: September 28, 2012
Received: October 1, 2012

Dear Dr. Komiyama:

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: K122078

Device Name: LoFric® Primo™ and LoFric® Hydro-Kit™

Indications for Use:

LoFric® Primo™ and LoFric® Hydro-Kit™ are 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)

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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
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