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510k SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Submitter and Contact Person:

AMSINO International, Inc
855 Towne Center Drive
Pomona, CA 91767
Jesus T. Farinas
Manager, Quality Assurance & Regulatory Affairs

AUG 10 2009

Establishment Number **2085175**

Name of the Device:

Classification Name: Urological Catheter/Catheter, Retention Type, Balloon

Proprietary Name: AMSURE® HYDROPHILIC LATEX FOLEY CATHETER

510k Number :

Regulation Number: **876.5130**

Class: **II**

Classification Product Code: **78 EZL**

Predicate Devices:

AMSURE® FOLEY CATHETER (k030120)
BARDEX I.C. Latex Foley Catheter (k040658)
BARDEX LUBRI-Sil All Silicon Lubricious Coated Foley Catheters (k070508)
BARDEX LUBRI-Sil Foley Catheters (k984084)

Intended use of the Device:

The AMSURE® HYDROPHILIC LATEX FOLEY CATHETER, is intended for use in the drainage of fluids from, and to the urinary tract/bladder.

Device Description:

The AMSURE® Hydrophilic *Latex* Foley Catheter is a retention type urological catheter made of silicone coated natural Latex material modified with the addition of a lubricious/hydrophilic coating to facilitate the insertion of the catheter. It consists of a double lumen drainage tube with 2 opposing drainage eyes at the distal end. One lumen drains fluid to and from the urinary tract, while the second lumen is for inflation and deflation of the balloon. On the opposing end of the shaft are a connecting funnel and a luer activated valve. This product is available in a combination of French sizes, balloon capacities and lengths to accommodate pediatric and adult male and female applications. The device will be offered in French sizes from 12Fr to 28Fr, balloon size of 5 cc and 16-28 Fr in balloon size of 30cc. The device is disposable, sterile (Ethylene Oxide sterilization) and for single use only. The coating has been tested for its safety and efficacy.

Fundamental Scientific Technology:

The catheter described in this premarket notification have similar technological features and performance as the predicate device(s). The catheters are manufactured from silicone coated natural latex material and have lubricious, hydrophilic coating that facilitates insertion of the catheter. The device under submission having the same material, manufactured in the same manner and having a lubricious coat function have the same intended use as currently marketed devices raise no new issues of safety and effectiveness and are substantially equivalent.

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COMPARISON TABLE OF THE FEATURES OF THE SUBJECT DEVICE TO THE PREDICATE DEVICE(S)

	Device on submission	Predicate device k030120	Bardex k040658	Bardex K070508	Bardex k984084
Material	Latex	Latex	Latex	Silicon	Silicon
Lumen	Dual	Dual	Dual	Dual	Dual
Lubricious coated	Yes	No	Yes	Yes	Yes
Sterile	Yes-EtO	Yes Gamma	Yes EtO	Yes EtO	Yes EtO
Biocompatibility	Meet Requirements	Meet Requirements	Meet Requirements	Meet Requirements	Meet Requirements
Intended Use	Drainage of fluids to/from urinary tract/bladder	Drainage of fluids to/from urinary tract	Drainage and/or collection and/or measurement of urine.	Drainage of fluids to/from urinary tract	Drainage of fluids to/from urinary tract

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DECLARATION OF CONFORMITY

(Special 510k: AMSURE® Hydrophilic Latex Foley Catheter)

I certify as the Vice President for Quality Assurance and Regulatory Affairs of Amsino International, that as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrate that the predetermined criteria were met. In addition, we certify that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

Gang Chen, VP Quality Assurance and Regulatory Affairs

2009-06-04

(Signature) **(Date)**

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

Mr. Jesus Farinas
Quality Assurance and Regulatory Affairs Manager
Amsino International, Inc.
855 Towne Center Drive
POMONA CA 91767

AUG 10 2009

Re: K091699
Trade/Device Name: AMSURE® HYDROPHILIC LATEX FOLEY CATHETER
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: July 20, 2009
Received: July 28, 2009

Dear Mr. Farinas:

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); 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): *k091699*

DEVICE NAME: *AMSURE® HYDROPHILIC LATEX FOLEY CATHETER*

INDICATIONS FOR USE:

The AMSURE® HYDROPHILIC LATEX FOLEY CATHETER, is intended for use in the drainage of fluids from, and to the urinary tract/bladder.

Prescription Use X *AND/OR* *Over-the Counter Use* _____
(Part 21 CFR801 Subpart D) *(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, Abdominal,
and Radiological Devices
510(k) Number K091699