510k SUMMARY

K101824

SEP 13 2010

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
Establishment Number	**2085175**
Name of the Device:	
Classification Name:	Urological Catheter/Catheter, Retention Type, Balloon
Proprietary Name:	*AMSURE® 3-WAY Hydrophilic Latex Foley Catheter*
510k Number:	
Regulation Number:	**876.5130**
Class:	**II**
Classification Product Code:	**78 EZL**

Predicate Devices:
AMSURE® HYDROPHILIC LATEX FOLEY CATHETER ***(k091699)***
AMSURE® FOLEY CATHETER ***(k030120)***
BARD, Bardex LubriSil 3-Way Foley Catheter ***(k002868)***
WELL-LEAD 3-Way Foley Catheter ***(k082815)***

Intended use of the Device:

The AMSURE® 3-Way Hydrophilic Latex Foley Catheter is intended to be used for bladder/urinary tract drainage and bladder/urinary tract irrigation for urological use only.

Device Description:

The *AMSURE® 3-WAY 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 insertion of the catheter. This device is a Latex tube with three lumens: one lumen for urinary drainage which is to be connected to a urine collecting container; one lumen with two-way valve for inflation/deflation of the foley balloon and one lumen for irrigation of the bladder/urinary tract. The 3-Way Hydrophilic Latex Foley Catheter is coated with a lubricious hydrophilic coating which

becomes slippery when wet. 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 adult male and female applications. The device will be offered in French sizes from 14Fr to 26Fr, balloon size of 5 cc and 30cc. The device is disposable, sterile (Ethylene Oxide Sterilization) and for single use only.

Fundamental Scientific Technology:

The catheter described in this premarket notification has 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.

The *AMSURE® 3-Way Latex Foley Catheter,* a modification of previously cleared device The *AMSURE® Hydrophilic Latex Foley Catheter* (k091699) is substantially equivalent to the predicate device in fundamental technology, performance, and material used. The *AMSURE® 3-Way Hydrophilic* Latex *Foley Catheter* is made of silicone coated natural latex material that is substantially equivalent to the predicate devices in fundamental technology, performance and intended use. A table of comparison of the features of the device to the predicate device is included on this submission.

The device under this submission has the same Indication For Use (drainage of fluids from the urinary tract/bladder and irrigation of urinary tract/bladder) as the predicate devices *Well Lead 3-Way Catheters, (k082815)* and *Bard's Bardex LubriSil 3-Way Foley Catheter(k00286).*

Performance Testing

The *Amsure® 3-Way Hydrophilic Latex Foley Catheter* was evaluated in accordance with ASTM F-623-99 and FDA's Guidance for Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters – February 27, 1997. The performance data is presented herewith to demonstrate conformance to the performance requirements.

Friction Test
Hydrophilic Coating Distribution
Hydrophilic Coating Uniformity
Flow rate through drainage and douche/irrigation lumens
Balloon Integrity
Balloon volume Integrity
Deflation reliability

Biocompatibility Testing

AMSINO International has determined that compliance to the Biocompatibility requirement based on the Blue Book Memorandum # G95-1, entitled: Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part I: Evaluation and Testing" has been met by virtue of the predicate device(s) being made of materials that have been well characterized and have a long history of safe use.

Sterilization

The *Amsure® 3-Way Hydrophilic Latex Foley Catheter* is sterilized by EtO as validated per ISO 11135-1:2007 –Sterilization of Healthcare Productts – Ethylene Oxide Part I: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices. Since the *Amsure® 3-Way Hydrophilic Latex Foley Catheter* is made of the same material, manufactured and processed in the same manner as the predicate device(s), *no additional sterilization validation is required.*

Substantial Equivalence

The *Amsure® 3-Way Hydrophilic Latex Foley Catheter* is substantially equivalent *as the predicate devices(s)* since it is made of the same material, manufactured and processed in the same manner; meets all Performance Testing per ASTM F623; complies with Biocompatibility Requirements per ISO 10993 and Sterilization per ISO 11135; as the predicate device(s). There are no new issues of safety and effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Jesus Farinas
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SEP 13 2010

Re: K101824
Trade/Device Name: AMSURE® 3-Way Hydrophilic Latex Foley Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: July 27, 2010
Received: August 6, 2010

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. 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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101824

SEP 13 2010

INDICATIONS FOR USE STATEMENT

510k number if known): ***k101824***

DEVICE NAME: *AMSURE® 3-WAY HYDROPHILIC LATEX FOLEY CATHETER*

INDICATIONS FOR USE:

AMSURE® 3-Way Hydrophilic Latex Foley Catheter is intended to be used for bladder/urinary tract drainage and bladder/urinary tract irrigation for urological use only.

PRECAUTIONS: Do not use petroleum based ointments or lubricants.

CONTRAINDICATIONS: Those individuals with known sensitivity or allergy to latex are excluded from the use o f this device. Product use should be discontinued should signs of sensitization occur.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___√___ *(Per 21 CFR 801.109)*

OR

Over-the Counter Use _____

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K101824