K091306

510(K) Summary of Safety and Effectiveness
AMSelf™ PVC Intermittent Catheter

Company:	Amsino International, Inc. 855 Towne Center Drive AUG 21 2009 Pomona,CA 91767 (909)626-5888
Contact:	Holiven Ji Manager of Regulatory Affairs
Date Prepared:	April 22, 2009
Classification Name:	Tray, Catheterization, Sterile Urethral, with or without Catheter (876.5130)
Common Name:	Urethral Catheter
Proprietary Name:	*AMSure*™ PVC Intermittent Catheter
Product Code:	FCM
Medical Specialty:	Gastroenterology/Urology
Device Class:	Class II
Unmodified Device:	*AMSure*™ Urethral Catheterization Tray (K030712)
Device Description:	The *AMSureTM* PVC Intermittent Catheter is a sterile, single-use patient device, compromising a PVC tubing and funnel.
Intended Use:	The *AMSure*™ PVC Intermittent Catheter is intended for use in the drainage of urine from the bladder.
Comparison to Predicate:	The *AMSure*™ PVC Intermittent Catheter is a configuration and label modification of the *AMSure*™ Urethral Catheterization Tray (K030712) and is intended for the same use.
Non-Clinical Testing:	Performance and biocompatibility testing has demonstrated the safety and effectiveness of the *AMSure*™ PVC Intermittent Catheter for its intended use.

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

AUG 21 2009

Mr. Holiven Ji
Manager of International Regulatory Affairs
Amsino International, Incorporated
855 Towne Center Drive
POMONA CA 91767

Re: K091306
Trade/Device Name: AMSure™ PVC Intermittent Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: July 20, 2009
Received: July 28, 2009

Dear Mr. Ji:

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 Statement

510(k) Number: K091306
(if known)

Device Name: ***AMSure*** PVC Intermittent Catheter

Indications for Use: The ***AMSure*** PVC Intermittent Catheter is intended for use in the drainage of urine from the bladder.

Prescription Use ___√___ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K091306