OCT 23 2008

510(K) Summary of Safety and Effectiveness
AMSelf™ Closed Catheterization System

Company: Amsino International, Inc.
855 Towne Center Drive
Pomona, CA 91767
(909) 626-5888

Contact: Ching Ching Seah, Ph.D.
Director of Regulatory Affairs

Date Prepared: September 24, 2008

Classification Name: Tray, Catheterization, Sterile Urethral, with or without Catheter (876.5130)
Common Name: Catheterization Kit
Proprietary Name: *AMSelf*™ Closed Catheterization System
Product Code: FCM
Medical Specialty: Gastroenterology/Urology
Device Class: Class II

Unmodified Device: *AMSure*™ Urethral Catheterization Tray (K030712)

Device Description: The *AMSelf*™ Closed Catheterization System is a single-use patient device, compromising a PVC urological catheter and a drainage bag assembled in a closed-system configuration.

Intended Use: The *AMSelf*™ Closed Catheterization System is intended for use in the drainage of urine from the bladder.

Comparison to Predicate: The *AMSelf*™ Closed Catheterization System is a configuration and assembly modification of the *AMSure*™ Urethral Catheterization Tray (K030712) and is intended for the same use.

Non-Clinical Testing: Performance and biocompatibility testing has demonstrated that the *AMSelf*™ Closed Catheterization System is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2008

Ching Ching Seah, Ph.D.
Director of Research, Development and Regulatory Affairs
Amsino International, Incorporated
855 Towne Center Drive
POMONA CA 91767

Re: K082831
Trade/Device Name: AMSelf™ Closed Catheterization System
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: FCM
Dated: September 24, 2008
Received: October 8, 2008

Dear Dr. Seah:

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 such 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); 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.

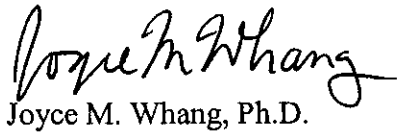
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,



Joyce M. Whang, Ph.D.
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: (if known)	K082831
Device Name:	*AMSelf*™ Closed Catheterization System
Indications for Use:	The *AMSelf*™ Closed Catheterization System is intended for use in the drainage of urine from the bladder.

Prescription Use ✓ (Per 21 CFR 801. 109)

OR

Over-The-Counter Use_____

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 K082831