510(K) Summary of Safety and Effectiveness
AMSure® Disposable Syringe with/without Needle

JUN 29 2006

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: January 20, 2006

Classification Name: Syringe, Piston (880.5860)
Hypodermic Single Lumen Needle (880.5570)

Common/Usual Name: Disposable hypodermic syringe

Proprietary Name: *AMSure*® Disposable Syringe with/without Needle

Product Code: FMF and FMI

Medical Specialty: General Hospital

Device Class: Class II

Predicate Devices: Monoject® Piston Syringes (K945715)
Nipro® Disposable Hypodermic Syringes with or without Needle (K051574)

Device Description: The *AMSure*® Disposable Syringe is a sterile, single-use hypodermic syringe with or without an attachable hypodermic needle. It consists of a syringe barrel, a plunger rod, a piston, a nozzle cap and/or a single lumen hypodermic needle. The *AMSure*® Needle is comprised of a metal tube sharpened at one end and joined to a female connector (hub) at the other end.

Intended Use: The *AMSure*® Disposable Syringe with/without Needle is intended for the injection of fluids into, or the withdrawal of fluids from parts of the body below the skin. *AMSure*® Needles are intended to mate with male nozzles of piston syringes or administration sets.

Comparison to Predicate: The *AMSure*® Disposable Syringe with/without Needle is similar to the predicate devices in operational principle, materials, design, technical characteristics and intended use. Any existing differences do not affect safety and effectiveness of the device.

Non-Clinical Testing: Performance and biocompatibility testing has demonstrated that the *AMSure*® Disposable Syringe with/without Needle 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

JUN 29 2006

Dr. Ching Ching Seah
Director of Research & Development and Regulatory Affairs
Amsino International, Incorporated
855 Towne Center Drive
Pomona, California 91767

Re: K061039
Trade/Device Name: AMSURE® Disposable Syringe with/without Needle
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF, FMI
Dated: April 14, 2006
Received: April 14, 2006

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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061039

Indications For Use

510(k) Number (if known): **K061039**

Device Name: ***AMSURE***® Disposable Syringe with/without Needle

Indications For Use:

The ***AMSURE***® Disposable Syringe with/without Needle is intended for the injection of fluids into, or the withdrawal of fluids from parts of the body below the skin. Needles are intended to mate with male nozzles of piston syringes or administration sets.

Prescription Use **X** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible]
[illegible] Physiology, General Hospital
[illegible] Control Dental Devices

K061039