

K093773

MAR 10 2010



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## SPECIAL 510k PREMARKET NOTIFICATION

February 11, 2010

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (WO66-0609)  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

### Reference:

Dear Madam/Sir:

AMSINO International, Inc. hereby submits this **Special 510(k)**: for *AMSURE® I.V. Administration Set*, a modification of our previously cleared *AMSURE® I.V. ADMINISTRATION SET (k973107)*. We consider our intent to market this device as confidential commercial information and requests that it be treated as such by FDA. We have taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me at (909) 626-5888, extension 127 or at [jesus\\_farinas@amsino.com](mailto:jesus_farinas@amsino.com)

Sincerely,

A handwritten signature in black ink, appearing to read "Jesus T. Farinas". The signature is stylized and cursive.

Jesus T. Farinas  
Manager, Quality Assurance and Regulatory Affairs

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center (WO66-0609)  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

February 11, 2010  
Re SPECIAL 510(k) Submission  
*AMSINO® I.V. ADMINISTRATION SET*

Attention Document Mail Clerk

AMSINO INTERNATIONAL, INC. is requesting marketing clearance for the *AMSINO® I.V. ADMINISTRATION SET*, a modification of a previously cleared device: *AMSURE® I.V. ADMINISTRATION SET*, (k973107) The premarket notification information required by 21 CFR 807.87 is as follows:

- a. Classification Name: *Set, Administration, Intravascular*
- b. Common/Usual Name: *I.V. Administration Set*
- c. FDA Establishment Registration Number: 2085175
- d. Owner/Operator Identification Number: 9008588
- e. Classification: *Class II device*  
Classification Number: *FPA*  
*880. 5440*

f. Statement of Intended Use:

The *AMSINO® I.V. ADMINISTRATION SET* is a device intended to administer fluids from a container to a patient's vascular system through a catheter inserted into a vein.

- g. Label/Labeling/Advertisements: A sample of the *AMSINO® I.V. ADMINISTRATION SET AND* package labeling are enclosed (Appendices 2 & 3).
- h. Substantial Equivalence: The *AMSINO® I.V. ADMINISTRATION SET* is made from the same material, manufactured and processed in the same manner and has the same intended use as the predicate device, the *AMSINO® I.V. ADMINISTRATION SET (k973107)*

In addition, the *AMSINO® I.V. ADMINISTRATION SET* is substantially equivalent to currently legally marketed predicate devices in material, technology and intended use as the *AMSINO® I.V. ADMINISTRATION SET (k971037)*.

**Statement of Technological Characteristic of the Device:**

The *AMSINO® I.V. ADMINISTRATION SET* meets the Bench performance testing requirement according to ISO 8536-4 when appropriate and/or AMSINO's testing and acceptance criteria: (see Appendix 4)

Closure Piercing Device (Spike) Features

Air Inlet Device Characteristics

Connector Performance criteria: i.e. to prevent leakage

Drip Chamber and Drip Tube Performance

Flow Regulator Performance

Flow characteristics

Tensile Strength of Connectors

Self-sealing injection site challenge test

The number of injection port access to failure for needleless port with valves, diaphragms or membranes.

**Biocompatibility and Hemocompatibility:** Biocompatibility assessment of the *AMSINO® I.V. ADMINISTRATION SET* has been conducted based on the guidelines established by various governmental and standard setting organizations such as ISO 10993-1- Biological Evaluation of Medical Devices. Based upon the results of this prolonged duration, indirect blood path containing device assessment; (Cytotoxicity, Sensitization, Irritation, Systemic Cytotoxicity and Hemocompatibility testing) the materials used to fabricate the *AMSINO® I.V. ADMINISTRATION SET*, have been shown to be biocompatible, hemocompatible, and appropriate for its intended use. (See Appendix 6)

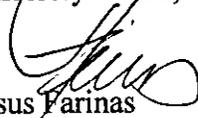
**Sterility:** *AMSINO® I.V. ADMINISTRATION SET* is sterilized by Ethylene Oxide as validated per ISO 11135-1:2007-Sterilization of Healthcare products – Ethylene Oxide - Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices. ( See Appendix 7)

**Pyrogenicity:** *AMSINO® I.V. ADMINISTRATION SET* is tested for pyrogenicity (see Bench Test table). (See Appendix 4)

**Microbial Ingress Challenge Test:** Amsino's testing of potential microbial ingress demonstrates a 4-log reduction of micro-organisms against gram negative and gram positive organisms using the proper aseptic technique. ( See Appendix 5)

**The *AMSINO® I.V. ADMINISTRATION* is substantially equivalent to the predicate devices in technology, materials used and intended use as the *AMSINO® I.V. ADMINISTRATION SET (k973107)*.**

Sincerely Yours,



Jesus Farinas

Manager, Quality Assurance and Regulatory Affairs

## SPECIAL 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 and Regulatory Affairs  
Telephone Number : (909) 626-5888, ext 127  
Email: [jesus\\_farinas@amsino.com](mailto:jesus_farinas@amsino.com)

**Establishment Number:** 2085175  
**Name of the Device:**  
**Classification Name:** Set, Administration, Intravascular  
**Proprietary Name:** *AMSINO® I.V. ADMINISTRATION SET*

**510k number:** k093773  
**Regulation Number:** 880.5440  
**Class:** II  
**Classification Product Code:** FPA

**Predicate Devices:**  
*AMSINO® I.V ADMINISTRATION SET (k973107)*

**Intended use of the Device:**  
The *AMSINO® I.V. ADMINISTRATION SET* is a device intended to administer fluids from a container to a patient's vascular system through a catheter inserted into a vein.

**Device Description:**  
The *AMSINO® I.V. ADMINISTRATION SET* is a single use, latex-free, Non-DEHP, gravity feed, sterile device sterilized with Ethylene Oxide Gas. It is used to administer fluids from a container to a patient's vascular system through a catheter inserted into a vein. It is comprised of various components such as: bag, spike, drip chamber (vented and non-vented), Y-site, burette, tubing, flow controller, drip selector, clamp, check valve, latex-free injection site, needleless injection site, flashbulb, filter, manifold, stopcock, flash bulb, luer connectors and bag hanger.

This submission is an extension of the original approval (k973107) and covers the following AMSINO Product Line:

AMSINO® STANDARD I.V. ADMINISTRATION SET  
AMSafe® I.V. ADMINISTRATION SET (*identical to the Amsino Standard I.V. Administration set, except it is marketed for Emergency Medical Services group/personnel*)

AMSafe3® I.V. ADMINISTRATION SET (*identical to AmSafe I.V. Administration Set, with the exception of the drip selector option.*)

AMSINO offers both standard and custom sets with tubing of various sizes and lengths with a choice of 10, 15, 20 and 60 drops per ml to meet customer requirements and specifications. Customers may request I.V. Administration sets with varying configuration containing any combination of the parts per the table:

Tubing	Bag Spike	Filter	Bag Hanger
Drip Chamber	Clamp	Rotating male luer lock	Y-site
Needleless injection site	Flow Controller	Male or Female luer lock	stopcock
Split Septum Injection Site	Drip Selector	Check Valve	manifold

**Technological Characteristics Summary:**

AMSINO® I.V. ADMINISTRATION SET is constructed of high grade extruded DEHP-free PVC. Component material list is herewith attached (see device drawings). The intended use, the basic design, function and the materials used to construct the IV Administration Set is identical to the predicate device and other devices currently legally marketed and are substantially equivalent. This premarket notification is an update of the performance and biocompatibility data of the currently approved predicate device – the Amsino I.V. Administration Set (k971037).

**Performance Data**

The AMSINO® I.V. ADMINISTRATION SET meets the **Bench performance testing** requirement according to ISO 8536-4 when appropriate and/or AMSINO's testing and acceptance criteria:

- Closure Piercing Device (Spike) Features
- Air Inlet Device Characteristics
- Connector Performance criteria: i.e. to prevent leakage
- Drip Chamber and Drip Tube Performance
- Flow Regulator Performance
- Flow characteristics
- Tensile Strength of Connectors
- Self-sealing injection site challenge test
- The number of injection port access to failure for needleless port with valves, diaphragms or membranes.

**Biocompatibility and Haemocompatibility:** Biocompatibility assessment of the *AMSINO® I.V. ADMINISTRATION SET* has been conducted based on the guidelines established by various governmental and standard setting organizations such as ISO 10993-1- Biological Evaluation of Medical Devices. Based upon the results of this prolonged duration, indirect blood path containing device assessment, (Cytotoxicity, Sensitization, Irritation, Systemic Cytotoxicity and Hemocompatibility testing) the materials used to fabricate the *AMSINO® I.V. ADMINISTRATION SET*, have been shown to be biocompatible, hemocompatible, and appropriate for its intended use. The test results indicate neither sensitivity, nor toxicity and slight irritation is associated with the *AMSINO I.V. Administration Set*. Test data demonstrate that the *AMSINO I.V. Administration Set* is haemocompatible.

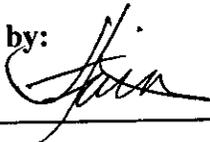
**Sterility:** *AMSINO® I.V. ADMINISTRATION SET* is sterilized by Ethylene Oxide as validated per ISO 11135-1:2007-Sterilization of Healthcare products – Ethylene Oxide - Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices.

**Pyrogenicity:** *AMSINO® I.V. ADMINISTRATION SET* is tested for pyrogenicity (see Bench Test table).

**Microbial Ingress Testing:** Amsino's testing of potential microbial ingress demonstrates a 4-log reduction of micro-organisms against gram negative and gram positive organisms using the proper aseptic technique.

**The *AMSINO® I.V. ADMINISTRATION SET* is substantially equivalent to the predicate devices in technology, materials used and intended use as the *AMSINO® I.V. ADMINISTRATION SET (k973107)*.**

Prepared by:



Jesus Farinas, QA/RA Manager

11 FEB 2010

Date



MAR 10 2010

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

Mr. Jesus T. Farinas  
Manager, Quality Assurance and Regulatory Affairs  
Amsino International, Incorporated  
855 Towne Center Drive  
Pomona, California 91767

Re: K093773  
Trade/Device Name: AMSINO® I.V. ADMINISTRATION SET  
Regulation Number: 21 CFR 880.5440  
Regulation Name: Intravascular Administration Set  
Regulatory Class: II  
Product Code: FPA  
Dated: February 11, 2010  
Received: February 12, 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.

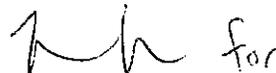
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



Anthony D. Watson, B.S., M.S., M.B.A.  
Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number: **k093773**

Device Name: **AMSINO® I.V. ADMINISTRATION SET**  
Indications For Use:

The **AMSINO® I.V. ADMINISTRATION SET** is a device intended to administer fluids from a container to a patient's vascular system through a catheter inserted into a vein.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

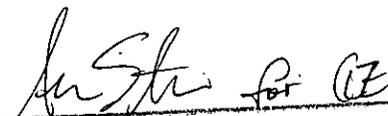
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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