September 7, 2018

Amsino International Inc.
Jane Gao
VP of R&D
708 Corporate Center Drive
Pomona, California 91768

Re: K181423
Trade/Device Name: AMSure Sterile Water, and Sterile Normal Saline for Wound Flush
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 9, 2018
Received: July 11, 2018

Dear Jane Gao:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181423

Device Name
AMSure® Sterile Water, and Sterile Normal Saline for Wound Flush

Indications for Use *(Describe)*

AMSure® Sterile Water, and Sterile Normal Saline for Wound Flush

- For over-the-counter use: For moistening absorbent wound dressing and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin.

- For prescription use: For moistening absorbent wound dressing and for moistening, debriding and cleaning acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second degree burns, cuts, abrasions and minor skin irritations and for device irrigation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section 5: 510(k) Summary (K181423)

a) Submitter Information:

Submitter: Amsino International Inc.
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Pomona, CA 91768
Phone: +1 (909)626-5888
Fax: +1 (909)626-3888

Contact Person: Jane Gao
Vice President of R&D, Amsino International Inc.
Cell phone: +86 – 139 -1614 – 7664
E-mail: Jane_gao@amsino.com

Date of Summary: August 30, 2018

b) **Device Information**:

Trade or Proprietary Name: *AMSure*® Sterile Water, and Sterile Normal Saline for Wound Flush

Common or Usual Name: Sterile Water and Sterile Saline for Wound flush

Regulatory Class: Unclassified, pre-amendment device

Product Code: FRO

c) **Identification of Legally Marketed Device(s)**:

- K172486: Anexa Wound Flush, Sterile Water and Sterile Normal Saline
- K083042: Wound Flush, Sterile Water and Sterile Normal Saline

d) **Device Description**:

AMSure® Sterile Water, and Sterile Normal Saline for Wound Flush devices are wound and device cleaning solutions that are intended for moistening and debriding of dermal wounds and for device irrigation. Sterile Water and sterile normal saline for wound flush are intended to be used in clinical or home care and should only be used by clinicians familiar with the treatment of possible complications.

The solution is either sterile water or sterile normal saline for irrigation and meets the requirements of USP<40>. The bottle and cap are made by HDPE, the inner induction sealed film is foil. The devices are offered in 100mL bottles.

e) **Statement of Device Intended Use**:

AMSure® Sterile Water, and Sterile Normal Saline for Wound Flush

- For over-the-counter use: For moistening absorbent wound dressing and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin.
- For prescription use: For moistening absorbent wound dressing and for moistening, debriding and cleaning acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second degree burns, cuts, abrasions and minor skin irritations and for device irrigation.

f) **Substantial Equivalence Discussion**:

- Technological Characteristics: The proposed device has the same technological characteristics and provide the same mechanism of action as the predicates' devices.
- Intended Use: The proposed device also labeled as same intended use as the predicates' devices.
- Material: The proposed device use same USP grade saline and water, same type of resin for the container. The biocompatibility testing of proposed device has been conducted and has been proof as non-cytotoxic, non-irritating and non-sensitizing with ISO10993 standard.

Comparison table between proposed device and Predicate Devices:

Table 5-1

	Subject	Predicate 1	Predicate 2	Results
Manufacturer	Amsino International Inc.	Anexa Biomedical, Inc.	Nurse Assist, Inc.	
K Number	K181423	K172486	K083042	
Classification	Unclassified Pre-amendment	Unclassified Pre-amendment	Unclassified Pre-amendment	Same
Product Code	FRO	FRO	FRO	Same
Indications for Use	1. For OTC 2. For Rx	1. For OTC 2. For Rx	1. For OTC 2. For Rx	Same
Principle of Operation	Mechanical action of fluid moving across the wound or device aids in the removal of foreign objects such as dirt and debris.	Mechanical action of fluid moving across the wound or device aids in the removal of foreign objects such as dirt and debris.	Mechanical action of fluid moving across the wound or device aids in the removal of foreign objects such as dirt and debris.	Same

Chemical composition	0.9% sterile saline or sterile water, no antimicrobial or other substance added	0.9% sterile saline or sterile water, no antimicrobial or other substance added	0.9% sterile saline or sterile water, no antimicrobial or other substance added	Same
Models	AS398 100mL USP Normal Saline AS399 100mL USP Sterile Water	8100-100mL USP Sterile water 9100- 100mL USP Sterile Saline 8250- 250mL USP Sterile Water 9250- 250mL USP Sterile Saline 8500- 500mL USP Sterile Water 9500- 500mL USP Sterile Saline 8120- 120mL USP Sterile Water 9120- 120mL USP Sterile saline	6250- 100mL USP Sterile Water 6240- 100mL USP sterile Saline 6260- 250mL USP Sterile Water 6270- 250mL USP Sterile Saline 6290- 500mL USP Sterile Water 6280- 500mL USP Sterile Saline 6210-120mL USP Sterile Water 6220- 120mL USP Sterile Saline	Similar
Sterility	Gamma Sterilization	Unsure	Gamma Sterilization	Same with K083042
Single Use/Reusable	Single Use	Single Use	Single Use	Same

Conclusion:

Sterile water and sterile normal saline have the same technological characteristics and provide the same mechanism of action as the predicates' devices. According to the above analysis, there's no major difference between the proposed devices and the predicated devices would impact the effectiveness and safety. The *AMSure*® Sterile Water, and Sterile Normal Saline for Wound Flush devices are therefore considered to be substantially equivalent to the above-mentioned predicates' devices.

g) **Nonclinical Testing (Bench)**:

The following performance testing was conducted on the proposed device:

- Biocompatibility testing has demonstrated the biological safety of the proposed devices which may directly or indirectly contact the patients.
- Performance testing has demonstrated the proposed devices which meet the standard on USP Sterile Saline and USP Sterile Water.
- Stability testing evaluated the properties of the *AMSure*® Sterile Water, and Sterile Saline for Wound Flush after accelerated aging in support of the labeling.

Performance testing conclusion: The results of the performance evaluation tests showed the *AMSure*® sterile water, and sterile normal saline for wound flush passed all acceptance criteria.

h) **Conclusions**:

The information provided within this pre-market notification demonstrates that *AMSure*® Sterile Water, and Sterile Normal Saline for Wound Flush has no difference that would affect the safety or effectiveness of the devices as compared to the predicate device and provide reasonable assurance of the safety and effectiveness of the devices to demonstrate substantial equivalency.