April 14, 2021

Amsino Medical Inc.
Torsten Nilson
President N.A.
700 Enterprise St. Aurora
Aurora, Illinois 60504

Re: K201138
Trade/Device Name: AMSure® Single Use Saline Topical Solution
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 8, 2021
Received: February 24, 2021

Dear Torsten Nilson:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lixin Liu, Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201138

Device Name
AMSure® Single Use Saline Topical Solution

Indications for Use *(Describe)*
For use in moistening and lubricating absorbent wound dressings for cuts, bruises and minor burns prior to removal from the wound area

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Traditional 510(k) Summary for K201138

a) Submitter Information:

Submitter:	Amsino Medical Inc.
	700 Enterprise St. Aurora, IL60504
	Phone: +1 (847)7721958
Contact Person:	Torsten Nilson
	President of North America Operations
	Mobil phone: Tel: +1 847 772 1958
	Email: Torsten_nilson@amsino.com
Date of Preparation:	April 10th, 2021

b) Device Information:

Device Trade Name:	*AMSure*® Single Use Saline Topical Solution
Common or Usual Name:	Single Use Saline Topical Solution
Classification Name:	Dressing, Wound, Drug
Product Code:	FRO
Regulation Number:	No
Device Class:	Unclassified
Review Panel:	General & Plastic Surgery panel

c) Identification of Legally Marketed Device(s):

Predicate device: K993969 SALJET single dose sterile saline topical solution.

d) Device Description:

The subject *AMSure*® Single Use Saline Topical Solution device is normal saline 0.9% w/v Sodium Chloride. It is used in moistening and lubricating absorbent wound dressings for cuts, bruises, and minor burns prior to removal from the wound area. They are intended to be used in clinical and should only be used by clinicians familiar with the treatment of possible complications.

The subject device of normal saline topical solution 0.9% w/v is a unit-dose low density polyethylene (LDPE) vial contains 0.9% w/v Sodium Chloride USP in Water for Injection USP. The formulation contains no additives. The subject device is using blow fill seal technology. The devices are offered in 15mL, 35mL, 50mL.

e) Indications for Use:

For use in moistening and lubricating absorbent wound dressings for cuts, bruises and minor burns prior to removal from the wound area.

f) Substantial Equivalence Discussion:

- Technological Characteristics: The subject device has the similar technological characteristics and provide the similar principle of operation as the predicate device.
- Intended Use: The subject device has the similar intended use as the predicate device.

Comparison between Subject Device and Predicate Devices

	Subject	Predicate
Manufacturer	Amsino International Inc.	Winchester Laboratories LLC.
510k Number	K201138	K993969
Classification	Unclassified Pre-amendment	Unclassified Pre-amendment
Product Code	FRO	FRO
Indications for Use	For use in moistening and lubricating absorbent wound dressings for cuts, bruises and minor burns prior to removal from the wound area.	For use in moistening and lubricating absorbent wound dressings for traumatic wounds, cuts, bruises and minor burns prior to removal from the wound area.
Type of Use	For Rx only	For Rx only
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.
Chemical composition	Solution: 0.9% normal saline, no antimicrobial or other substance added Container: Low density polyethylene	Solution: 0.9% sterile saline, no antimicrobial or other substance added Container: Low density polyethylene
Models	AS0159: 15 mL Single Use Saline Topical Solution AS0359: 35 mL Single Use Saline Topical Solution AS0509: 50mL Single Use Saline Topical Solution	Saljet 6 30ml of sterile normal saline 0.9% w/v, six vials per carton Saljet 40 30ml of sterile normal saline 0.9% w/v, 40 vials per carton

Sterility	Aseptic blow fill seal	Sterile
Single Use/Reusable	Single Use	Single Use
Shelf life	2 years	n/a

The subject device is similar in both indications for use and technological characteristics when compared to the predicate device. The subject device and the predicate device have similar labeling, instructions for use and packaging. The difference between the subject device and the predicate is the sterility status. The subject device undergoes aseptic process with blow-fill-seal technology during manufacturing process while the predicate device is terminal sterilized. However, this difference does not affect the safety of the device as evidenced by the aseptic process validation and biocompatibility testing conducted on the subject device. This difference does not affect the effectiveness of the subject device based on the fact that the mechanism of action for both the predicate device and the subject device is provided by mechanical action of fluid moving across the wound or device aids in the removal of foreign objects such as dirt and debris.

g) Nonclinical Testing (Bench):

The following performance testing was conducted on the selected representative device:

- Design verification testing was conducted to ensure the device met the predetermined acceptance criteria for the following tests: Identify Assay % NaCl, pH, Endotoxin, Sterility, Leak Testing, Net Fill Volume were performed to demonstrate that the subject device met predetermined acceptance criteria per specification of AMSure® Single Use Saline Topical Solution.
- Biocompatibility testing: Biocompatibility evaluation was conducted in accordance with the FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The battery of testing included the following tests and assessments. In Vitro Cytotoxicity (per ISO10993-5), Acute Systemic Toxicity (per ISO10993-11), Intracutaneous Reactivity (per ISO10993-10), Skin Sensitization (per ISO10993-10), material-mediated pyrogenicity (per USP <151>) and chemical characterization and toxicological risk assessment.

h) Conclusions:

Based on a comparison of composition, technological characteristics, intended use and biocompatibility test results, we conclude that AMSure® Single Use Saline Topical Solution is as safe and effective and is substantially equivalent to the predicate device.