March 22, 2022

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

Re: K213522
Trade/Device Name: *AMSafe*® Pre-Filled Normal Saline Flush Syringe
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: NGT
Dated: March 8, 2022
Received: March 14, 2022

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/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,

Clarence W. Murray, III, Ph.D.
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)*
K213522

Device Name
AMSafe® Pre-Filled Normal Saline Flush Syringe

Indications for Use *(Describe)*
The AMSafe® Pre-Filled Normal Saline Flush Syringe, is intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices. Use according to the recommendations of the manufacturer for the appropriate device.

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.

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K213522 Summary

a) Submitter Information:

Submitter:	Amsino International Inc. 708 Corporate Center Drive Pomona, CA 91768 Phone: +1 (909)626-5888 Fax: +1 (909)626-3888
Contact Person:	Jane Gao VP of R&D of Amsino International Cell phone: +86 139 1614 7664 Jane_gao@amsino.com
Date of Summary:	March 22, 2022

b) **Device Information**:

Trade or Proprietary Name:	*AMSafe*® Pre-Filled Normal Saline Flush Syringe
Common or Usual Name:	Pre-Filled Normal Saline Flush Syringe
Classification Name:	Saline, vascular access flush
Product Code:	NGT
Regulation Number:	880.5200
Device Classification:	II
Review Panel:	General Hospital

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

AMSafe® Pre-Filled Normal Saline Flush Syringe, 510(k) number K183473.

d) **Device Description**:

AMSafe® Pre-Filled Normal Saline Flush Syringe is a polypropylene plastic syringe filled with 0.9% sodium chloride for injection, USP, and capped with a polypropylene syringe tip cap.

e) **Indications for Use**:

The *AMSafe*® Pre-Filled Normal Saline Flush Syringe, is intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices. Use according to the recommendations of the manufacturer for the appropriate device.

f) **Technological Characteristics Comparison**:

The main difference between subject device and the predicate device are different material suppliers and adding an extra thread to the plunger rod and inside of plunger stopper, and subject device is terminally sterilized by steam sterilization. The device will be marketed as 10mL syringe with a 3mL, 5mL or 10mL fill volume, and a 5mL syringe with 3mL or 5mL fill volume according to the market needs. The products are in PP wrapper as a dust cover for non-

sterile field.

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

Comparison between subject device and predicate device.

Table 5-1

Device Characteristic	Subject device	Predicate device (K183473)	Discussion
Indications for Use	The AMSafe® Pre-Filled Normal Saline Flush Syringe, is intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices. Use according to the recommendations of the manufacturer for the appropriate device.	The AMSafe 0.9% sodium chloride pre-filled normal saline flush syringe, is intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices. Use according to the recommend at ions of the manufacturer for the appropriate device.	Identical
Prescription/ over-the counter use	For Rx only	For Rx only	Identical
Operation Principle	The AMSafe® Pre-Filled Normal Saline Flush Syringe is a three-piece, sterile, single use syringe with a 6% (Luer) connector pre-filled with 0.9% Sodium Chloride Injection, USP, and sealed with a tip cap.	The AMSafe® Pre-Filled Normal Saline Flush Syringe is a three-piece, sterile, single use syringe with a 6% (Luer) connector pre-filled with 0.9% Sodium Chloride Injection, USP, and sealed with a tip cap.	Identical
Design	The subject device has modified to add an extra thread to the plunger rod and inside of plunger stopper, the female Luer cap has	Prefilled Normal Saline plastic piston syringe with Luer lock connection fitting and non-vented, female Luer lock tip cap	Identical

	changed to screw type.		
Chemical composition	0.9% Sodium chloride injection, USP	0.9% Sodium chloride injection, USP	Identical
Syringe material	Barrel and plunger: polypropylene Stopper: Chlorobutyl rubber (not made with natural rubber latex) Tip cap: polypropylene with white colorant	Barrel and plunger: polypropylene Stopper: Butyl rubber (not made with natural rubber latex) Tip cap: polypropylene with white colorant	Different
Syringe Size and Fill Volumes	Fill 3ml, 5ml, 10ml in 10cc syringe Fill 3ml, 5ml in 5cc syringe	Fill 3ml, 5ml, 10ml volume in 12cc syringe Fill 20ml volume in 20cc syringe	Different
Syringe packaging	PP wrap	PP wrap or Sterile barrier Plastic peel pouch	Similar
Sterilization method and SAL Level	Terminally sterilized by steam, 10^{-6} SAL	Terminally sterilized by Gamma radiation, 10^{-6} SAL	Different
Labeled non-pyrogenic	Yes	Yes	Identical
Single use only	Yes	Yes	Identical
Shelf Life	3 years	2 years	Different

g) **Summary of Non-clinical Testing (Bench):**

The non-clinical testing for *AMSafe*® Pre-Filled Normal Saline Flush Syringe was performed to demonstrate verification testing in conformance with the acceptance criteria of test methods and recognized consensus standards shown below.

The following performance testing was conducted on the proposed device:

Table 5-2

ID#	Test	Method	Acceptance criteria	Conclusion
1	**Physical testing of syringe**	ISO7886-1 ISO80369-7	ISO7886-1 ISO80369-7	Pass
	Integrity test of package	ASTM F2338-09	No leakage	Pass
	Dimension test	ISO80369-7	ISO80369-7	Pass
	Lubricant of syringe test	ISO7886-1	ISO7886-1	Pass
	Dead space test	ISO7886-1	ISO7886-1	Pass
	Limits of acidity or alkalinity of syringe	ISO7886-1	ISO7886-1	Pass
2	**Sodium Chloride Injection, USP Testing**			
	pH value	USP<791>	PH: 4.5-7.0	Pass
	Chemical Identification Tests	USP<191>	USP<191>	Pass
	0.9% normal saline content test	USP6-466	0.86% -- 0.94%	Pass
	Oxidizable substance test	USP6-471	USP6-471	Pass
	Iron test	USP<241>	< 2ppm	Pass
	Ammonium	USP<191>	USP<191>	Pass
	Calcium	USP<191>	USP<191>	Pass
	Carbonate	USP<191>	USP<191>	Pass
	Sulfate	USP<191>	USP<191>	Pass
	Total organic carbon	USP<643>	USP<643>	Pass
	Limits of extractable metals	USP<233> USP<232>	USP<233> USP<232>	Pass
3	**Particulate matter**	USP<788>	≥10um, ≤6000 ≥25um, ≤600	Pass
4	**Biocompatibility testing**			
	Bacterial endotoxins test	USP<85>	Bacterial endotoxins≤0.5EU/mL	Pass
	Acute systemic toxicity	ISO10993-11	No systemic toxicity	Pass
	Intracutaneous reactivity	ISO10993-10	Non-irritant	Pass
	Pyrogen test	ISO10993-11	Non-pyrogen	Pass
	Skin sensitization	ISO10993-10	Non-sensitizer	Pass

	In vitro cytotoxicity	ISO10993-5	Non-cytotoxic	Pass
	In vitro hemolysis properties	ASTM F756-17	Non-hemolytic	Pass

The shelf life of the final finished sterilized device was evaluated according to the recognized consensus standard ASTM F1980-16 to verify that the subject device will remain within specification during the prescribed shelf life when stored under the labeled storage conditions.

h) **Conclusions**:

The conclusions drawn from the nonclinical tests demonstrate that the *AMSafe*® Pre-Filled Normal Saline Flush syringe is as safe as effective, and performs as well as or better than the legally marketed device