July 12, 2019

Amsino International, Inc.
Jim Barley
RA/QA Consultant
708 Corporate Center Drive
Pomona, California 91768

Re: K183473
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: June 6, 2019
Received: June 13, 2019

Dear Jim Barley:

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,

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183473

Device Name
AMSafe® Pre-Filled Normal Saline Flush Syringe

Indications for Use *(Describe)*
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 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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Traditional 510(k) Summary (As required by 21 CFR 807.92(a)) For K183473

a) Submitter Information:

Submitter:	Richard Lee, CEO of Amsino Amsino International Inc. 708 Corporate Center Drive Pomona, CA 91768 Phone: +1 (909)626-5888 Fax: +1 (909)626-3888
Contact Person:	Jim Barley, RA/QA Consultant Cell phone: 949-4333058 jimbarley@aol.com
Date of Summary:	July 9, 2019

b) Device Information:

Trade or Proprietary Name: AMSafe® Pre-Filled Normal Saline Flush Syringe

Common or Usual Name:	Pre-Filled Normal Saline Flush Syringe
Regulation Number:	21 CFR 880.5200
Classification:	II
Product Code:	NGT

c) Identification of Legally Marketed Device(s):

Predicate Device: AM USA 0.9% Sodium Chloride Flush Syringe, 510(k) number K133685, 20 cc Syringe with 20 cc fill volume

Reference Devices:

- For Fluid Path Only Sterile: AM USA 0.9% Sodium Chloride Flush Syringe, 510(k) number K111034, 12 cc Syringe with 3, 5, 10 cc fill volumes
- For Device provided Sterile: AM USA 0.9% Sodium Chloride Flush Syringe, 510(k) number K120836, 12 cc Syringe with 3, 5, 10 cc fill volumes

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 cap. The device will be terminally sterilized by gamma radiation sterilization. The device will be marketed as a 12mL syringe with a 3mL, 5mL, or 10mL fill volume, and a 20mL syringe with 20mL fill volume. The products are in two different packages, one is poly blister package and the entire packaged device are gamma radiation sterilized for sterile delivery to a sterile field; another is PP wrapper as a dust cover for non-sterile field.

The solution is sterile normal saline for injection and meets the requirements of

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USP<40>.

e) Intended Use:

AMSafe® Pre-Filled Normal Saline Flush Syringe

This device is intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices. It is intended for single use only.

f) Technological Characteristics

Shown below is a side by side comparison of the subject device with the predicate device.

Table 5-1

Device Characteristic	Proposed device	Primary Predicate device (K133685)	Reference device 1 (K120836)	Reference device 2 (K111034)	Results
Indications for Use	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.	Intended use: 0.9% sodium chloride flush syringes are intended for use in flushing compatible intravenous administratio n sets and indwelling intravenous access devices. Use according to the recommend at ions of the manufacturer for the appropriate device	Intended use: 0.9% sodium chloride flush syringes are intended for use in flushing compatible intravenous administratio n sets and indwelling intravenous access devices. Use according to the recommend at ions of the manufacturer for the appropriate device.	Intended use: 0.9% sodium chloride flush syringes are intended for use in flushing compatible intravenous administrati on sets and indwelling intravenous access devices. Use according to the recommend at ions of the manufacture r for the appropriate device.	Same
Design	Prefilled plastic piston syringe with Luer lock connection	Prefilled plastic piston syringe with Luer lock connection	Prefilled plastic piston syringe with Luer lock connection	Prefilled plastic piston syringe with Luer lock connection	Same

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	fitting and non-vented, female Luer lock tip cap	fitting and non-vented, female Luer lock tip cap	fitting and non-vented, female Luer lock tip cap	fitting and non-vented, female Luer lock tip cap	
Syringe Size and Fill Volumes	3ml, 5ml, 10ml in 12cc syringe 20ml in 20cc syringe	20ml in 20cc syringe	3ml, 5ml, 10ml in 12cc syringe	3ml, 5ml, 10ml in 12cc syringe	Similar
Fill Volume Graduations	On syringe label	On syringe label	On syringe label	On syringe label	Same
Syringe Content	0.9% Sodium chloride injection, USP	0.9% Sodium chloride injection, USP	0.9% Sodium chloride injection, USP	0.9% Sodium chloride injection, USP	Same
Labeled non-pyrogenic	Yes	Yes	Yes	Yes	Same
Single use only	Yes	Yes	Yes	Yes	Same
Sterile	Yes	Yes	Yes	Yes	Same
Devices with Fluid Path Only Sterile Or Devices provided sterile	Devices with Fluid Path Only Sterile Or Devices provided sterile	Devices provided sterile	Devices provided sterile	Devices with Fluid Path Only Sterile	Same
Shelf Life	2 years	2 years	2 years	2 years	Same
Sterilization method	Terminally sterilized by Gamma radiation, 10-6 SAL	Terminally sterilized by Gamma radiation, 10-6 SAL	Terminally sterilized by Gamma radiation, 10-6 SAL	Terminally sterilized by Gamma radiation, 10-6 SAL	Same

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Syringe material	Barrel and plunger: polypropyle ne Plunger: Butyl rubber (not made with natural rubber latex) Tip cap: polypropylene with white colorant	Barrel and plunger: polypropylene Plunger: Butyl rubber (not made with natural rubber latex) Tip cap: polypropylene and TPE	Barrel and plunger: polypropylene Plunger: Butyl rubber (not made with natural rubber latex) Tip cap: polypropylene and TPE	Barrel and plunger: polypropylene Plunger: Butyl rubber (not made with natural rubber latex) Tip cap: polypropyle ne and TPE	Similar
Syringe packaging	PP wrap or Sterile barrier Plastic peel pouch	Sterile barrier Plastic peel pouch	Sterile barrier Plastic peel pouch	PP wrap	Same
Content of Syringe Package	One syringe per pouch	One syringe per pouch	One syringe per pouch	One syringe per pouch	Same

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

The non-clinical testing for *AMSafe® Pre-Filled Normal Saline Flush Syringe* was performed to demonstrate verification and validation testing in conformance with the acceptance criteria of test methods and recognized consensus standards shown below.
Table 5-2

ID#	Test	Method	Acceptance criteria	Result/Conclusion
1	**Plastic syringe**	ISO7886-2017	ISO7886-2017	Conforms/Pass
2	**Sodium Chloride Injection, USP Testing**			
	pH value	USP40<791>	PH: 4.5-7.0	Pass
	Limits of extractable metals of saline solution	USP<233>, <232>	USP<233>, <232>	Pass
	Chemical Identification Tests	USP <191>	USP <191>	Pass
	0.9% normal saline content test	VP200	0.86% -- 0.94%	Pass

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	Oxidizable substance test	VP200	VP200	Pass
	Iron test	USP40<241>	< 2ppm	Pass
	Ammonium	USP40<191>	USP40<191>	Pass
	Calcium	USP40<191>	USP40<191>	Pass
	Carbonate	USP40<191>	USP40<191>	Pass
	Sulfate	USP40<191>	USP40<191>	Pass
	Particulate matter	USP 40 <788>	≥10um, ≤6000; ≥25um, ≤600.	Pass
3	**Biocompatibility testing**			
	Bacterial endotoxins test	USP40<85>	Bacterial endotoxins≤0.25 EU/mL	Pass
	Acute system toxicity	ISO10993-11	The device extracts did not ellicit a systemic response	Pass
	Irritation / Intracutaneous reactivity	ISO10993-10	Non-irritant	Pass
	Material-mediated pyrogenicity	ISO10993-11	Non-pyrogenic response	Pass
	Sensitization	ISO10993-10	Non-sensitizer	Pass
	Cytotoxicity	ISO10993-5	Non-cytotoxic	Pass
	Hemolysis	ISO10993-4 (ASTM F756)	Non-hemolytic	Pass
	Chemical characterization	USP<232>, USP<233>	Acceptable extractable / leachable profile	Pass
4	**Blister package integrity**			
	Seal strength test	ASTM F88/F88M-15	Should not be less than 2 N/ inch	Pass
	Dye integrity test	ASTM F1929-15	ASTM F1929-15	Pass

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The shelf life of the final finished sterilized device was evaluated using the recognized consensus standard on the requirements for materials, sterile barrier systems and packaging systems for terminally sterilized medical devices (ISO11607-1)

h) Conclusions:

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