August 12, 2023

Anhui Tianyang Pharmaceutical Co., Ltd.
Zhang Shunlin
Quality Manager
46 Tiantong Road, Tianchang City, Anhui Province
Tianchang, Anhui
China

Re: K223584
Trade/Device Name: Pre-Filled Normal Saline Flush Syringe
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: NGT
Dated: July 13, 2023
Received: July 14, 2023

Dear Zhang Shunlin:

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,

Bifeng Qian -S

Bifeng Qian, M.D., 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)*
K223584

Device Name
Pre-Filled Normal Saline Flush Syringe

Indications for Use *(Describe)*
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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510(k) Summary (K223584)

I 510(k) Submitter

Device Submitter: Anhui Tianyang Pharmaceutical Co., LTD.
No.46, Tiantong Road, Tianchang City, Anhui Province

Contact Person: Zhang Sunlin
Quality Manager
Phone: +86-15805509075
E-mail: 752322508@qq.com

II Device

Trade Name of Device:	Pre-Filled Normal Saline Flush Syringe
Regulation Number:	21 CFR 880.5200
Classification Name:	Saline, Vascular Access Flush
Product Code:	NGT
Regulation Number:	21 CFR 880.5200
Regulatory Class	II
Review Panel	General Hospital

III Predicate Devices

510k Number	K213522
Trade Name of Device:	*AMSafe*® Pre-Filled Normal Saline Flush Syringe
Regulation Number:	21 CFR 880.5200
Regulation Name:	Intravascular Catheter
Regulatory Class	II
Product Code:	NGT

IV Device Description

Pre-Filled Normal Saline Flush Syringe is a polypropylene syringe filled with 0.9% sodium chloride for injection. It contains 3ml, 5ml and 10ml and consists of tip cap, barrel, piston, and plunger. This is a single use, disposable device(s), provided sterile.

V Indications for use

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.

VI Technological Characteristics Comparison

VI-1: Comparison of Pre-Filled 0.9% Normal Saline Flush Syringe

Device Characteristic	Subject Device (K223584)	Predicate Device (K213522)	Discussion
Indications for Use	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® PreFilled 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.	Similar Comment 1
Prescription/ over-the counter use	For Rx only	For Rx only	Identical
Operation Principle	The Pre-Filled Normal Saline Flush Syringe is flushed after the locking connector is connected to the medical catheter connector for clinical use the liquid medicine (0.9% sodium chloride injection) was pushed into the medical catheter and used to close and flush the end of the catheter in the gap between different drugs.	The AMSafe® PreFilled 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 with Luer lock connection fitting and nonvented, female Luer lock tip cap.	The device has modified to add an extra thread to the plunger rod and inside of plunger stopper, the female Luer cap has Changed to screw type.	Different Comment 2
Chemical composition	0.9% Sodium chloride injection, USP	0.9% Sodium chloride injection, USP	Identical
Syringe material	Tip Cap, Barrel and Plunger: polypropylene; Piston: Bromobutyl rubber	Barrel and plunger: polypropylene Stopper: Butyl rubber (not made with natural rubber	Identical

Device Characteristic	Subject Device	Predicate Device (K213522)	Discussion
		latex) Tip cap: polypropylene with white colorant	
Syringe Size and Fill Volumes	Fill 3ml, 5ml, 10ml in 10cc syringe Fill 3ml, 5ml in 5cc syringe	Fill 3ml, 5ml, 10ml in 10cc syringe Fill 3ml, 5ml in 5cc syringe	Identical
Syringe Packaging	BOPP heat sealing film	PP wrap	Different Comment 3
Sterilization method and SAL Level	Terminally sterilized by steam, 10^{-6} SAL	Terminally sterilized by steam, 10^{-6} SAL	Identical
Labeled nonpyrogenic	Yes	Yes	Identical
Singe Use Only	Yes	Yes	Identical
Shelf Life	2 Years	3 Years	Similar

Comment 1: The Indications for Use of the predicate and subject device are same and the intended use is same, which does not affect the safety and effectiveness of the product.

Comment 2: The Luer cap of the predicate device has been modified, and the subject device is a standard Luer connector that meets the requirements of ISO 80369-7, so it does not affect the safety and effectiveness of the product.

Comment 3: The packaging materials of the subject and predicate are different, but the packaging of the subject device has been verified, and the sterility of the product can be guaranteed within the claimed shelf life of 2 years. Therefore, the safety and effectiveness of the product will not be affected.

VII Summary of Non-clinical Testing (Bench)

The non-clinical testing for 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. Real time aged samples from three non-consequtive lots were tested for all performance criteria.

Table VII-1: Performance testing was conducted on the subject device

ID#	Test	Method	Acceptance Criteria	Conclusion
1	**Physical Testing of Syringe**			

1.1	Lubricant	ISO7886-1	ISO7886-1	Pass
1.2	Dead Space	ISO7886-1	ISO7886-1	Pass
1.3	Limits for acidity or alkalinity	ISO7886-1	ISO7886-1	Pass
1.4	Syringe Luer Performance	ISO 80369-7	ISO 80369-7	Pass
1.5	Sealing performance	ISO7886-1	ISO7886-1	Pass
2	**Sodium Chloride Injection, USP Testing**			
2.1	pH value	USP<791>	PH: 4.5-7.0	Pass
2.2	Oxidizable substance test	USP6-471	USP6-471	Pass
2.3	Carbonate	USP<191>	USP<191>	Pass
2.4	Sulfate	USP<191>	USP<191>	Pass
2.5	Calcium	USP<191>	USP<191>	Pass
2.6	Ammonium	USP<191>	USP<191>	Pass
2.7	Iron test	USP<241>	＜ 2ppm	Pass
2.8	Limits of extractable metals	USP<233> USP<232>	USP<233> USP<232>	Pass
3	**Particulate Contamination**	AAMI TIR42:2021	≥10μm, ≤6000 ≥25μm, ≤600	≥10μm, ≤361.5 ≥25μm, ≤0.0
4	**Biocompatibility Testing**			
4.1	Bacterial Endotoxins Test	USP 43<85>	Bacterial endotoxins≤ 0.5EU/mL	Pass
4.2	In Vitro Cytotoxicity	ISO 10995-5:2009	Non-cytotoxic	Pass
4.3	Intracutaneous Reactivity Test	ISO 10995-23:2021	Non-irritant	Pass
4.4	Skin Sensitization Test	ISO 10993-10:2021	Non-sensitizer	Pass
4.5	Acute Systemic Toxicity Test	ISO 10993-11:2017	No systemic toxicity	Pass
4.6	Pyrogen Test	ISO 10993-11:2017	Non-pyrogen	Pass
4.7	In Vitro Hemolysis Test	ISO 10993-4:2017	Non-hemolytic	Pass

VIII Clinical Test Conclusion

No clinical study is included in this submission.

IX Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject Pre-Filled Normal

Saline Flush Syringe is as safe as effective, and performs as well as or better than the legally marketed device.

Date of Summary: August 8, 2023