September 27, 2023

Hantech Medical Device Co., Ltd.
Arnold Yang
Vice President of Quality
No 288 Sanheng Road, Changhe Industrial Park, Cixi
Ningbo, Zhejiang 315326
China

Re: K231363
Trade/Device Name: Hantech Pre-filled 0.9% Normal Saline Flush Syringes (Models PFS-1003, PFS-1005, PFS-1010)
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: NGT
Dated: August 31, 2023
Received: August 31, 2023

Dear Arnold Yang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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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)*
K231363

Device Name
Hantech Pre-filled 0.9% Normal Saline Flush Syringes (Models PFS-1003, PFS-1005, PFS-1010)

Indications for Use *(Describe)*
The Hantech Pre-filled 0.9% Normal Saline Flush Syringes, are 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 (K231363)

I Submitter

Device submitter: Hantech Medical Device Co., Ltd.
No 288, Sanheng Road Changhe Industrial Park, Cixi 315326, Ningbo
PEOPLE'S REPUBLIC OF CHINA

Contact person:
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Date: 09/25/2023

II Device

Trade Name of Device: Hantech Pre-filled 0.9% Normal Saline Flush Syringes (Models PFS-1003, PFS-1005, PFS-1010)
Common Name: Pre-filled 0.9% Normal Saline Flush Syringes
Regulation Number: 21 CFR 880.5200
Classification: II
Classification Name: Saline, vascular access flush
Product code: NGT
Review Panel: General Hospital

III Predicate Devices

Trade name:	AMSafe® Pre-Filled Normal Saline Flush Syringe
Common name:	Pre-Filled Normal Saline Flush Syringe
Classification:	Class II, 21 CFR 880.5200
Product Code:	NGT
Premarket Notification:	K213522
Manufacturer:	Amsino International Inc.

IV Device description

The Hantech Pre-filled 0.9% Normal Saline Flush Syringes is a polypropylene plastic syringe filled with 0.9% sodium chloride for injection, USP, and capped with a polypropylene syringe tip cap. The device will be marketed as 10mL syringe with a

3mL, 5mL or10mL fill volume according to the market needs. It is terminally sterilized by steam sterilization. The product has a shelf life of 1 years.

Specification and Model	Syringe Size (mL)	Content of 0.9% sodium chloride injection, USP (mL)
PFS-1003	10	3
PFS-1005	10	5
PFS-1010	10	10

V Indications for use

The Hantech Pre-filled 0.9% Normal Saline Flush Syringes, are 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 Comparison of technological characteristics with the predicate devices

The Hantech Pre-filled 0.9% Normal Saline Flush Syringes have the same intended use, technology and design as the predicate device, and performance specifications are either identical or similar to the existing legally marketed predicate device.The device will be marketed as 10mL syringe with a 3mL, 5mL or 10mL fill volume of 0.9% Sodium chloride injection, USP according to the market needs. The differences between the Pre-filled 0.9% Normal Saline Flush Syringes and predicate device do not alter suitability of the proposed device for its intended use.

Device feature	Subject Device	Predicate Device K213522	Comments
Indications for use	The Hantech Pre-filled 0.9% Normal Saline Flush Syringes, are 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® 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.	Same
Product code	NGT	NGT	Same
Regulation number	21 CFR 880.5200	21 CFR 880.5200	Same
Class	CLASS II	CLASS II	Same
Prescription/ over-the	For Rx only	For Rx only	Same

Device feature	Subject Device	Predicate Device K213522	Comments
counter use			
Principle of operation	The product 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 protective 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.	Same
Chemical composition	0.9% Sodium chloride injection, USP	0.9% Sodium chloride injection, USP	Same
Syringe material	Barrel and plunger: polypropylene Plunger Stopper: Butyl rubber (not made with natural rubber latex) Protective cap: polypropylene	Barrel and plunger: polypropylene Stopper: Chlorobutyl rubber (not made with natural rubber latex) Tip cap: polypropylene with white colorant	Different Comment 1
Syringe Size and Fill Volumes	Fill 3ml, 5ml, 10ml in 10cc syringe	Fill 3ml, 5ml, 10ml in 10cc syringe Fill 3ml, 5ml in 5cc syringe	Same
Syringe packaging	PP wrap	PP wrap	Same
Sterilization method and SAL Level	Terminally sterilized by steam, 10^{-6}SAL	Terminally sterilized by steam, 10^{-6} SAL	Same
Single use only	Yes	Yes	Same
Shelf life	1 years based on real time aging study	3 years	Different Comment 2

Discussion:

Comment 1

The materials of plunger stopper and protective cap are different between the subject device and predicate device. The cap materials of subject device and predicate device are all polypropylene, the only difference is that the cap material of the predicate device has white colorant while the subject device does not. The biocompatibility test of the subject device was conducted to demonstrate that the subject device met the biocompatibility requirements. So these differences do not raise any safety and effectiveness problems.

Comment 2

The shelf life is different between the subject device and predicate device. The subject device has a shelf life of 1 years and meets all acceptance criteria. Results from shelf life testing conducted on the subject device demonstrate that differences (if any) between the shelf life of the predicate device and the subject device shelf life do not raise different questions of safety and effectiveness.

VII Summary of Non-clinical Testing (Bench):

The non-clinical testing for Hantech Pre-filled 0.9% Normal Saline Flush Syringes were 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:

NO.	Test	Method	Acceptance criteria	Conclusion
1	Physical testing of syringe	ISO7886-1 ISO80369-7	ISO7886-1 ISO80369-7	Pass
	Appearance	ISO7886-1	ISO7886-1	Pass
	Scale and label	ISO7886-1	ISO7886-1	Pass
	Sliding performance test	ISO7886-1	ISO7886-1	Pass
	Dimension test	ISO80369-7	ISO80369-7	Pass
	Dead space test	ISO7886-1	ISO7886-1	Pass
	Limits of acidity or alkalinity of syringe	ISO7886-1	ISO7886-1	Pass
	Chemical performance	ISO7886-1	ISO7886-1	Pass
2	Sodium Chloride Injection, USP Testing			
	pH value	USP40-<791>	PH: 4.5-7.0	Pass
	Sodium identification	USP-<191>	USP-<191>	Pass
	Chlorine identification	USP-<191>	USP-<191>	Pass
	Content determination	USP<Sodium Chloride Injection>	95% ~ 105% (g/l)	Pass
	Oxidizable substance test	USP6-471	USP6-471	Pass

	Iron test	USP<Sodium Chloride Injection> USP40-<241>	<2ppm	Pass
	Ammonium salt	USP-<191>	USP-<191>	Pass
	Calcium salt	USP-<191>	USP-<191>	Pass
	Carbonate	USP-<191>	USP-<191>	Pass
	Sulfate	USP-<191>	USP-<191>	Pass
	Limits of extractable metals	USP<233> USP<232>	Cd≤2 μg/L Pb≤5 μg/L As≤15 μg/L Hg≤3 μg/L	Pass
3	Particulate matter	USP<788>	≥10um, ≤6000 ≥25um, ≤600	Pass
4	Biocompatibility testing			
	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	ISO 10993-4 ASTM F756-17	Non-hemolytic	Pass
5	Sterilization			
	Bacterial endotoxins test	USP<85>	Bacterial endotoxins ≤0.5EU/mL	Pass
	Sterility tests	USP31-<71>	USP31-<71>	Pass

The sterilization method has been validated according to ISO17665-1, which has thereby determined the routine control and monitoring parameters. The shelf life of the Hantech Pre-filled 0.9% Normal Saline Flush Syringes are determined based on stability study which includes ageing test. The shelf life of the final finished sterilized

device was evaluated based on real time aging study to verify that the subject device will remain within specification during the prescribed shelf life when stored under the labeled storage conditions.

Summary of clinical Testing: N/A

VIII Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the Hantech Pre-filled 0.9% Normal Saline Flush Syringes proposed in this 510(k) is as safe, as effective, performs as well as or better than the legally marketed device.