August 11, 2020

Nurse Assist, LLC
Romeo Crisologo
Vice President of Quality
4409 Haltom Road
Haltom City, Texas 76117

Re: K201286
Trade/Device Name: 0.9% Sodium Chloride I.V. Flush Syringe for Sterile Delivery, 1 syringe/pouch
0.9% Sodium Chloride I.V. Flush Syringe for Sterile Delivery, 2 syringes/pouch
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: NGT
Dated: May 13, 2020
Received: May 14, 2020

Dear Romeo Crisologo:

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 CAPT Elizabeth Claverie, M.S.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201286

Device Name

0.9% Sodium Chloride I.V. Flush Syringe for Sterile Delivery, 1 syringe/pouch
0.9% Sodium Chloride I.V. Flush Syringe for Sterile Delivery, 2 syringes/pouch

Indications for Use *(Describe)*

0.9% Sodium Chloride I.V. Flush Syringe for Sterile Delivery is intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices. Use according to the recommendations for the appropriate device. May be placed on a sterile field.

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.

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510(k) Summary

K201286

I. Submitter

Nurse Assist, LLC
4409 Haltom Road
Haltom City, TX 76117
Phone: 817-231-1300
Fax: 817-231-1500

Contact Person: Romeo Crisologo, Vice President of Quality
Date Prepared: August 10, 2020

II. Device

Device Proprietary Name:	0.9% Sodium Chloride I.V. Flush Syringe for Sterile Delivery, 1 syringe/pouch 0.9% Sodium Chloride I.V. Flush Syringe for Sterile Delivery, 2 syringes/pouch
Common or Usual Name:	Saline Intravascular Flush
Classification Name:	Saline, Vascular Access Flush
Regulation Number:	21 CFR 880.5200
Product Code:	NGT
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- Praxiject™ 0.9% NaCl, K171109, MedXL Inc.

The following reference device is cited within the submission:

- Normal Saline Flush, K150143, Nurse Assist, Inc.

IV. Device Description

The 0.9% Sodium Chloride I.V. Flush Syringe for Sterile Delivery is a sterile, single-use, pre-filled 12 mL syringe containing 10 mL of 0.9% Sodium Chloride Injection, USP. The pre-filled syringes are provided in two packaging configurations: 1) single syringe or 2) two (2) syringes.

The device may be used in the sterile field as they are sterilized post-packaging.

V. Indications for Use

0.9% Sodium Chloride I.V. Flush Syringe for Sterile Delivery is intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices. Use according to the recommendations for the appropriate device. May be placed on a sterile field.

VI. Comparison of Technological Characteristics

The table below compares key technological features between the subject and predicate devices.

Parameter	**0.9% Sodium Chloride I.V. Flush Syringe for Sterile Delivery (K201286)**	**Praxiject™ 0.9% NaCl (K171109)**	**Comparison**
Indications for Use	0.9% Sodium Chloride I.V. Flush Syringe for Sterile Delivery is intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices. Use according to the recommendations for the appropriate device. May be placed on a sterile field.	The Praxiject™ 0.9% NaCl prefilled syringe with 0.9% Sodium Chloride Injection, USP, is intended only for flushing vascular access devices. May be placed on a sterile field.	Similar
Design	Prefilled plastic piston syringe with Luer lock connection fitting and non-vented, female Luer lock tip cap	Prefilled plastic piston syringe with Luer lock connection fitting and non-vented, female Luer lock tip cap	Same
Syringe Size and Fill Volumes	10 mL in 12 cc syringe	3 mL in 5 cc syringe 5 mL in 5 cc syringe 3 mL in 10 cc syringe 5 mL in 10 cc syringe 10 mL in 10 cc syringe	Different
Fill Volume Gradations	On syringe label	On syringe label	Same
Syringe Content	0.9% Sodium Chloride Injection, USP	0.9% Sodium Chloride Injection, USP	Same

Parameter	0.9% Sodium Chloride I.V. Flush Syringe for Sterile Delivery (K201286)	Praxiject™ 0.9% NaCl (K171109)	Comparison
Labeled Non-Pyrogenic	Yes	Yes	Same
Single Use Only	Yes	Yes	Same
Sterile	Yes	Yes	Same
Use in sterile field	Yes	Yes	Same
Sterilization Method	Gamma irradiation	Gamma irradiation	Same
Shelf Life	2 years	2 years	Same
Syringe Material	- Barrel and piston: Polypropylene - Plunger: Synthetic isoprene (not made with natural rubber latex) - Tip Cap: Polypropylene and EBS with white colorant	- Barrel and Plunger: Polypropylene - Plunger: Bromobutyl rubber (Not made with natural rubber latex) - Tip Cap: ABS with white colorant	Different
Syringe Packaging	Plastic peel pouch (printed on one side, clear on the other)	Plastic peel pouch (printed on one side, clear on the other)	Same
Content of Syringe Package	One or two syringe(s) per pouch	One syringe per pouch	Different

Discussion

The 0.9% Sodium Chloride I.V. Flush Syringe for Sterile Delivery and the predicate devices share the following characteristics:

- intended use;
- design;
- fill volume;
- syringe content;
- sterilization method; and
- syringe packaging.

The 0.9% Sodium Chloride I.V. Flush Syringe for Sterile Delivery is technologically different from the predicate devices as follows:

- syringe size;
- syringe materials; and
- content of syringe packaging.

VII. Summary of Non-Clinical Testing

The following non-clinical data demonstrate that the testing met the acceptance criteria of the mentioned standards shown below:

Test Methodology/Standard	Purpose of the Test	Acceptance Criteria	Results
Cytotoxicity per ISO 10993-5:2009	To determine cytotoxic potential of the test article.	Per ISO 10993-5:2009	Pass
Irritation/Intracutaneous Reactivity per ISO 10993-10:2010	To evaluate the test article for irritation/intracutaneous reactivity.	Per ISO 10993-10:2010	Pass
Sensitization per ISO 10993-10:2010	To evaluate the test article for sensitization.	Per ISO 10993-10:2010	Pass
Acute Systemic Toxicity per ISO 10993-11:2017	To evaluate the test article for systemic toxicity.	Per ISO 10993-11:2017	Pass
Material-mediated Pyrogenicity per ISO 10993-11:2017 and USP <151>	To evaluate the test article for material mediated pyrogenicity.	Per ISO 10993-11:2017 and USP <151>	Pass
Hemocompatibility per ISO 10993-4:2006 and ASTM F756:2008	To evaluate the test article for hemolysis.	Per ISO 10993-4:2006 and ASTM F756:2008	Pass
Extractables/leachables per ISO 10993-18:2005	To evaluation the test article for extractables/leachables	Acceptable extractable/leachable profile	Pass
Package integrity	To verify pouch seal integrity	No visible damage/degradation of seal.	Pass
Real time and accelerated stability testing	To verify that product conforms to established specifications through its labeled shelf life.	See below for individual test acceptance criteria	Pass
- Fill volume/weight loss		10.4 mL +/- 0.4 mL. Weight loss over time ≤ 10%	Pass
- Pouch seal strength		≥ 0.46 lbs./in.	Pass
- Sterility per USP <71>		Absence of organisms	Pass
- Visual inspection		No holes, tears, or channels in seals. No damage to syringe.	Pass
- Color/odor		Fluid must be colorless and odorless.	Pass
- Assay of Sodium Chloride (per USP monograph)		95.0% - 105.0% NaCl	Pass

Test Methodology/Standard	Purpose of the Test	Acceptance Criteria	Results
- pH per USP <791>		4.5 to 7.0	Pass
- Identity per USP <191>		Successful identification	Pass
- Sub-visible particulate per USP <788>		≥ 10µm: ≤ 6000 part/syringe ≥ 25µm: ≤ 600 part/syringe	Pass
- Visible particulate per USP <790>		No visible particulate.	Pass
- Bacterial Endotoxin per USP <85>		≤ 0.25 EU/mL	Pass
- Iron/heavy metals		Iron, ≤ 2 ppm Heavy metals, ≤ 10 ppm	Pass
Sterilization Validation in accordance with ANSI/AAMI/ISO TIR 13004:2013	To establish the minimum irradiation dose required to achieve sterility.	10^{-6} SAL	Pass

VIII. Conclusion

The non-clinical tests demonstrate that the 0.9% Sodium Chloride I.V. Flush Syringe is as safe, as effective, and performs as well as or better than the legally marketed device.