July 13, 2023

MedXL Inc.
Hina Saini
Regulatory Affairs Specialist
285 Avenue Labrosse
Pointe-Claire, QC H9R 1A3
Canada

Re: K231754
Trade/Device Name: Praxiject™ 0.9% NaCl
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: NGT
Dated: June 12, 2023
Received: June 15, 2023

Dear Hina Saini:

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
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and Infection Control 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.

Submission Number *(if known)*

K231754

Device Name

Praxiject™ 0.9% NaCl

Indications for Use *(Describe)*

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.

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

July 12, 2023

Submission Number:	**K231754**
Device Trade Name:	Praxiject™ 0.9% NaCl
Common Name:	Saline Flush Syringe
Classification Name:	Saline, Vascular Access Flush
Product Code:	NGT
Regulation:	21 CFR §880.5200
Regulatory Class:	Class II
Classification Panel:	General Hospital
Submitter/Manufacturer:	MedXL Inc. 285 Av. Labrosse Pointe Claire, Quebec H9R 1A3, Canada Tel: (+1) 514.693.3150 Fax: (+1) 514.695.1511
Regulatory Contact:	Hina Saini, Regulatory Affairs Specialist

Primary Predicate Device

Device Trade Name:	Praxiject™ 0.9% NaCl
510(k) Number:	K192414
Classification:	Class II, 21 CFR §880.5200, Saline, Vascular Access Flush
Product Code:	NGT

Reference Device

Device Trade Name:	Praxiject™ 0.9% NaCl
510(k) Number:	K171109
Classification:	Class II, 21 CFR §880.5200, Saline, Vascular Access Flush
Product Code:	NGT

Device Description

The Praxiject™ family of 0.9% NaCl prefilled syringes marketed in the U.S.A. includes the following models: 37043US (3 mL/5 cc), 3704US (5 mL/5 cc), 37053US (3 mL/10 cc), 37055 US (5 mL/10 cc), 3705CUS (10 mL/10 cc), 3705-1US (10 mL/10 cc) and 3706US (20 mL/20 cc). These devices are single use plastic piston syringes with a Luer lock connection fitting, prefilled to labeled volume with 0.9% Sodium Chloride Injection USP, with no preservatives (normal saline), and capped with a plastic tip cap. Model 3705-1US (10 mL/10 cc) is individually packaged in a heat-sealed foil pouch, all other models are individually packaged in a heat-sealed peel pouch. All Praxiject™ 0.9% NaCl prefilled syringes are terminally sterilized by gamma irradiation.

Device Modifications

MedXL has extended the Praxiject™ 0.9% NaCl prefilled syringe family to include an additional model with 20 mL fill volume in a 20 cc piston syringe (20 mL/20 cc) individually packaged in a thicker heat-sealed peel pouch to account for the increased size and weight of the syringe. The 20 mL/20 cc model is distributed in a standard size shipping carton containing 6 cases of 60 syringes each. The modified Praxiject™ 0.9% NaCl prefilled syringe family contains 0.9% Sodium Chloride Injection USP that is produced by MedXL to USP specifications and current recognized quality standards.

Intended Use / Indications for Use

The Praxiject™ 0.9% NaCl prefilled syringe with 0.9% Sodium Chloride Injection, USP, is intended only for flushing of vascular access devices. May be placed on a sterile field.

Comparison of Technological Characteristics Between the Subject Device and the Primary Predicate and Reference Devices

The modified Praxiject™ 0.9% NaCl prefilled syringe is identical to the primary predicate device and reference device in fundamental technology, product design and materials, operating principles, and performance characteristics for the intended use. The differences in technological characteristics have been addressed by material and device component qualification, biocompatibility studies, stability studies, process and packaging validation, and finished product release testing in conformance with recognized consensus standards. A side-by-side comparison of device characteristics is presented in the following table.

Device Characteristic	Primary Predicate Device Praxiject™ 0.9% NaCl (K192414)	Reference Device Praxiject™ 0.9% NaCl (K171109)	Subject Device Praxiject™ 0.9% NaCl (K231754)	Comparison
Indications for Use	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.	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.	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.	Identical
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	Prefilled plastic piston syringe with Luer lock connection fitting and non-vented, female Luer lock tip cap.	Identical
Syringe Size and Fill Volumes	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	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	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 20 mL in 20 cc syringe	Different. New 20mL/20cc model produced to same standards
Fill Volume Graduations	On syringe label	On syringe label	On syringe label	Identical

Device Characteristic	Primary Predicate Device Praxiject™ 0.9% NaCl (K192414)	Reference Device Praxiject™ 0.9% NaCl (K171109)	Subject Device Praxiject™ 0.9% NaCl (K231754)	Comparison
Syringe Content	0.9% Sodium Chloride Injection USP	0.9% Sodium Chloride Injection USP	0.9% Sodium Chloride Injection USP	Same USP specifications but produced by MedXL to current quality standards
Labeled Non-pyrogenic	Yes; Bacterial Endotoxin testing per USP <85> and <161>: ≤ 0.5 EU/mL	Yes; Bacterial Endotoxin testing per USP <85> and <161>: ≤ 0.5 EU/mL	Yes; Bacterial Endotoxin testing per USP <85> and <161>: ≤ 0.5 EU/mL	Identical
Single Use Only	Yes	Yes	Yes	Identical
Sterile	Yes	Yes	Yes	Identical
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	Identical
Use on Sterile Field	Yes	Yes	Yes	Identical
Shelf Life	2 years	2 years	2 years	Identical
Syringe Material	Barrel and Plunger: Polypropylene Piston: Bromobutyl rubber (Not made with natural rubber latex) Tip Cap: ABS with white colorant	Barrel and Plunger: Polypropylene Piston: Bromobutyl rubber (Not made with natural rubber latex) Tip Cap: ABS with white colorant	Barrel and Plunger: Polypropylene Piston: Bromobutyl rubber (Not made with natural rubber latex) Tip Cap: ABS with white colorant	Identical
Syringe Packaging	Plastic peel pouch (printed on one side, clear on the other) – all sizes and fill volumes OR Aluminum foil pouch (printed on one side) – 10 mL in 10 cc syringe	Plastic peel pouch (printed on one side, clear on the other) – all sizes and fill volumes	Plastic peel pouch (printed on one side, clear on the other) – all sizes and fill volumes; thicker plastic used for 20 mL/20cc prefilled syringe OR Aluminum foil pouch (printed on one side) – 10 mL in 10 cc syringe	Different pouch material thickness for the 20mL/20cc model. Same performance specifications
Content of Syringe Package	One syringe per pouch	One syringe per pouch	One syringe per pouch	Identical
Shipping Package Configuration	100 syringes (10 cc) or 120 syringes (5cc) per case / 6 cases per shipping carton – all sizes and fill volumes in plastic peel pouch	100 syringes (10 cc) or 120 syringes (5cc) per case / 6 cases per shipping carton – all sizes and fill volumes in plastic peel pouch	60 syringes (20cc), 100 syringes (10 cc), or 120 syringes (5cc) per case / 6 cases per shipping carton – all sizes and fill volumes in plastic peel pouch	Different packaging quantity for 20 mL/20cc model.

Device Characteristic	Primary Predicate Device Praxiject™ 0.9% NaCl (K192414)	Reference Device Praxiject™ 0.9% NaCl (K171109)	Subject Device Praxiject™ 0.9% NaCl (K231754)	Comparison
	OR 115 syringes per double bag / 4 double bags per shipping carton – only 10 mL in 10 cc syringe in aluminum foil pouch		OR 115 syringes per double bag / 4 double bags per shipping carton – only 10mL in 10cc syringe in aluminum foil pouch	Same performance specifications

Summary of Non-Clinical Testing

The design and manufacturing of Praxiject™ 0.9% NaCl prefilled syringes are subject to verification and validation testing in conformance with regulatory guidance and recognized consensus standards. Below is a summary of the non-clinical testing and manufacturing controls that apply to this device modification.

Device Specification	Standard	Acceptance Criteria
Piston Syringe Testing (Each production lot)		
Design and Performance Requirements	ISO 7886-1; ISO 80369-7 (ISO 594-1 and ISO 594-2)	Conformity to standards and device specifications
Finished Device Testing (Each production lot)		
- **Appearance of Solution**	USP <790> / Visual inspection	Clear and colorless; Free of visible foreign solid particles
- **Solution Volume**	ISO 7886-1, USP <1151>	3 mL in 5 cc syringe: 3.0–3.4 mL 3 mL in 10 cc syringe: 3.0–3.6 mL 5 mL in 5 cc syringe: 5.0–5.6 mL 5 mL in 10 cc syringe: 5.0–6.0 mL 10 mL in 10 cc syringe: 10.0–11.0 mL 20 mL in 20 cc syringe: 20.0-22.0 mL
- **Assay**	USP Sodium Chloride Injection	0.855 – 0.945% (w/v)
- **Identification**	USP <191> Sodium and Chloride	Meets USP requirements
- **Bacterial Endotoxins**	USP <85>, USP <161>	≤ 0.5 USP EU/mL
- **Particulate Matter**	USP <788>	Particles ≥ 10 µm: ≤ 6000/syringe; Particles ≥ 25 µm: ≤ 600/syringe
- **pH**	USP <791>	4.5 – 7.0
- **Elemental Impurities**	USP <232> and USP <233> (Class I elements)	Arsenic: < 1.5 µg/g Cadmium: < 0.2 µg/g Lead: < 0.5 µg/g Mercury: < 0.3 µg/g
- **Iron**	USP <241>	≤ 2 ppm
- **Syringe Closure Integrity**	ISO 7886-1, ISO 594-2 (Adapted solution leakage test)	No damage, no leakage past piston and syringe tip cap
- **Pouch Integrity**	ASTM D3078 (Vacuum bubble emissions test)	No stream of bubbles; no leaks

Device Specification	Standard	Acceptance Criteria
Sterility and Shelf-life Testing (Design Verification and Validation)		
Sterility of Solution and Syringe Exterior	USP <71>	Sterile
Sterilization Method Validation	ISO 11137-1, ISO 11137-2, USP <61> (Terminal sterilization by gamma radiation)	SAL 10^{-6}
Shelf-life (Stability Study)	FDA Guidance: Shelf Life of Medical Devices (1991); FDA Guidance: Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products (2003)	Device specifications must be maintained for the labeled shelf life
Distribution Simulation Testing (Design Verification and Validation)		
Device & Package Integrity	ASTM D4169 (Distribution Cycle 13, Assurance Level II); ISO 11607-1; ASTM F1886 (Visual seal integrity verification); ASTM D3078 (Vacuum bubble emissions test); ISO 7886-1 and ISO 594-2 (Syringe and tip cap integrity verification)	No structural damage to shipping carton; Pouch/seal integrity – No seal defects; no stream of bubbles and no leaks during vacuum bubble emissions testing; Syringe integrity – No critical damage, no leaks past syringe cap or gasket; Luer lock (tip cap) connection – No cracks, no leaks
Biocompatibility Testing (Design Verification and Validation)		
Biological Evaluation	ISO 10993-1; FDA Guidance: Use of International Standard ISO 10993-1, Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process (2020)	Compliant process and evaluation for external communicating devices intended for indirect blood path contact with limited duration
Chemical Characterization (Extractables/Leachables)	ISO 10993-18, ISO 10993-17 USP <467>	Acceptable extractables/leachables profile; Negligible risk of health hazard
Cytotoxicity	ISO 10993-5	Non-cytotoxic
Sensitization	ISO 10993-10	Non-sensitizer
Irritation	ISO 10993-23	Non-irritant
Hemolysis	ISO 10993-4 (ASTM F756)	Non-hemolytic
Acute Systemic Toxicity	ISO 10993-11	Non-toxic
Pyrogenicity	ISO 10993-11 (USP <151>)	Non-pyrogenic

Summary of Clinical Testing

Clinical testing was not required for this device modification.

Conclusion

The conclusions drawn from the non-clinical testing demonstrate that the modified Praxiject™ 0.9% NaCl prefilled syringe, is as safe, as effective, and performs as well as or better than the legally marketed primary predicate device.