February 13, 2020

MedXL Inc.
Premala Premanathan
Regulatory Affairs Associate
285 Av Labrosse
Pointe-Claire, H9R 1A3 Ca

Re: K192414
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: January 16, 2020
Received: January 21, 2020

Dear Premala Premanathan:

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,

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)*

K192414

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
K192414

February 3, 2020

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) 514.695.7474 Fax: (+1) 514.695.1511
Regulatory Contact:	Premala Premanathan, Regulatory Affairs Associate

Predicate 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™ 0.9% NaCl prefilled syringe is a single use plastic piston syringe 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. Each prefilled syringe is individually packaged in a heat-sealed pouch and terminally sterilized by gamma irradiation.

Device Modification

The reason for this submission is the extension to the Praxiject™ 0.9% NaCl prefilled syringe line to include an additional 10 mL prefilled syringe model individually packaged in an aluminum foil pouch (as compared to the plastic peel pouch used for the predicate device models). The subject device model is distributed in four double bags with 115 syringes per double bags (as compared to six cases with 100 syringes (10 cc) or 120 syringes (5 cc) per case of the predicate device models) within a standard size shipping carton.

Intended Use / 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.

Technological Characteristics Comparison Table

Shown below is a side-by-side comparison of key device characteristics between the subject device and the predicate device.

Device Characteristic	Predicate Device Praxiject™ 0.9% NaCl (K171109)	Subject Device Praxiject™ 0.9% NaCl (K192414)	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.	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.	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	Identical
Fill Volume Graduations	On syringe label	On syringe label	Identical
Syringe Content	0.9% Sodium Chloride Injection, USP	0.9% Sodium Chloride Injection, USP	Identical
Labeled Non-pyrogenic	Yes	Yes	Identical
Single Use Only	Yes	Yes	Identical
Sterile	Yes	Yes	Identical
Use on Sterile Field	Yes	Yes	Identical
Sterilization Method	Terminally sterilized by gamma radiation, 10^{-6} SAL	Terminally sterilized by gamma radiation, 10^{-6} SAL	Identical
Shelf Life	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	Identical

Device Characteristic	Predicate Device Praxiject™ 0.9% NaCl (K171109)	Subject Device Praxiject™ 0.9% NaCl (K192414)	Comparison
Syringe Packaging	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 OR Aluminum foil pouch (printed on one side) – 10 mL in 10 cc syringe	Different
Content of Syringe Package	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	100 syringes (10 cc) or 120 syringes (5cc) per case / 6 cases per shipping carton – all sizes and fill volumes in plastic peel pouch OR 115 syringes per double bag / 4 double bags per shipping carton – 10 mL in 10 cc syringe in aluminum foil pouch	Different

The subject device, Praxiject™ 0.9% NaCl prefilled syringe, compares identical to the predicate device in intended use, indications for use, fundamental technology, product design, operating principles, and performance characteristics. The only difference between the subject device and the predicate device is in the primary protective packaging and shipping package configuration of the additional 10 mL prefilled syringe model.

Summary of Non-Clinical Testing

Shown below is a summary of the non-clinical testing that was performed with the subject device. The testing below was performed to demonstrate that the subject device meets the identified standards for this device type.

Test Methodology / Standard	Purpose	Acceptance Criteria	Results
Visual inspection of pouch seals per ASTM F1886	To verify pouch seal integrity	No visible unsealed areas, channels/pathway across width of seal, tears/holes: Reject on detection*	Conforms
		Undersealed areas, oversealed areas (hard/brittle seal), narrow seals (thinning along length of seal): non defective seal width should be greater than 67% of nominal seal width*	Conforms
Bubble emission test of pouch per ASTM D3078	To verify the integrity of the product packaging (pouch)	No leaks (no bubbles emitted upon immersion, no fluid inside the package)	Conforms

Test Methodology / Standard	Purpose	Acceptance Criteria	Results
Visual inspection of prefilled syringe for damage	To ensure the prefilled syringe is not damaged in a way that would prevent its use	No critical damage (consistent with instructions for use); no leaks	Conforms
Test for liquid leakage and resistance of luer lock fitting	To ensure the prefilled syringe is adequately sealed	No leaks; no cracks	Conforms
Test for integrity of printed label per ASTM F2250	To verify the integrity of the printed information is adequate for the intended use environment	Print must remain defined and legible, color must not lighten, ink must not run (Slight smudging of ink or transfer to swab is allowable)	Conforms
Test of formulation per Sodium Chloride Injection USP monograph:	To verify formulation of the Sodium Chloride solution meets the USP requirements	See below for individual test acceptance criteria:	Conforms (See below)
- Assay of Sodium Chloride (per USP monograph)		0.855 to 0.945% NaCl	Conforms
- pH per USP<791>		4.5 to 7.0	Conforms
- Identification of Sodium and Chloride per USP <191>		Successful identification	Conforms
- Particulate matter per USP <788>		≥ 10µm: ≤ 6000 part/syringe ≥ 25µm: ≤ 600 part/syringe	Conforms
- Bacterial Endotoxins per USP <85>		≤ 0.5 EU/mL	Conforms
- Elemental Impurities (Heavy Metals) per USP<232>/ <233> (Class I elements)		Arsenic: ≤ 1.5µg/g Cadmium: ≤ 0.2µg/g Mercury: ≤ 0.3µg/g Lead: ≤ 0.5µg/g	Conforms
- Iron per USP <24>		Iron: ≤ 2ppm	Conforms
Distribution cycle (Transport) Validation per ASTM D4169, Distribution Cycle 13	To ensure the packaging maintains product integrity under anticipated shipping and handling conditions	Packaging and syringe integrity per ISO 11607-1	Conforms
Sterilization Validation	To establish the minimum irradiation dose required to render the product sterile	10^{-6} SAL per ISO 11137-2	Conforms

Conclusion

The conclusions drawn from the nonclinical testing for the subject device, Praxiject™ 0.9% NaCl prefilled syringe, demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.