February 27, 2024

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

Re: K233623
Trade/Device Name: Praxiject™ SP 0.9% NaCl
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: NGT
Dated: January 31, 2024
Received: January 31, 2024

Dear Faiza Benazza:

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,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233623

Device Name
Praxiject™ SP 0.9% NaCl

Indications for Use *(Describe)*
For vascular access devices flushing only. Sterile fluid path only. Not for use 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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MedXL Inc. | 285 Labrosse, Pointe-Claire (QC), Canada, H9R 1A3
T : +1 514.695.7474 | F : +1 514.695.1511 | www.medxl.com

510(k) Summary - K233623

February 23, 2024

Device Trade Name:	Praxiject™ SP 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
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:	Faiza Benazza, Regulatory Affairs Specialist

Predicate Device

Device Trade Name:	Praxiject™ 0.9% NaCl
510(k) Number:	K231754
Classification:	Class II, 21 CFR §880.5200, Saline, Vascular Access Flush
Product Code:	NGT

Device Description

The Praxiject™ SP 0.9% NaCl prefilled syringe is a single use plastic piston syringe with a Luer lock connection fitting, prefilled to labeled volume of 10mL with 0.9% Sodium Chloride Injection, USP, with no preservatives (normal saline), and capped with a plastic tip cap. The Praxiject™ SP 0.9% NaCl prefilled syringe is designed to maintain a sterile fluid path only and is individually packaged in a clear flexible plastic film, flow-wrapped heat-sealed pouch that functions only as a protective barrier (dust cover). The device is terminally sterilized by gamma irradiation.

Intended Use / Indications for Use

For vascular access devices flushing only. Sterile fluid path only. Not for use on a sterile field.

Comparison of Technological Characteristics

The Praxiject™ SP 0.9% NaCl prefilled syringe is similar to the predicate device in intended use, indications for use, fundamental technology, operating principles, and performance characteristics. Technological differences in tip cap design and in syringe form and packaging of the Praxiject™ SP 0.9% NaCl that is supplied with a sterile fluid path only have been addressed by labeling and conformity to consensus standards. A side-by-side comparison of key device characteristics is presented in the following table:

Device Characteristic	**Predicate Device Praxiject™ 0.9% NaCl (K231754)**	**Subject Device Praxiject™ SP 0.9% NaCl**	**Comparison Analysis**
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.	For vascular access devices flushing only. Sterile fluid path only. Not for use on a sterile field.	Same indications for use and intended use with explicit labeling to indicate that the subject device is designed to maintain a sterile fluid path only and it is not suitable for use on a sterile field.
Syringe 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 slip tip cap	Different. Luer slip tip cap design and syringe form factor differences. Devices meet the same safety and performance standards.
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 20 mL in 20 cc syringe	10 mL in 10 cc syringe	Different. The subject device is supplied only in one syringe size and fill volume, within the range offered with the predicate device.
Fill Volume Graduations	On syringe label	On syringe label	Identical.
Syringe Content (normal saline)	0.9% Sodium Chloride Injection, USP	0.9% Sodium Chloride Injection, USP	Identical.
Non-pyrogenic	Yes	Yes	Identical.
Single Use Only	Yes	Yes	Identical.
Sterile Device	Yes	Sterile Fluid Path Only	Different. The difference in use environment is addressed by labeling and distinct packaging.
Sterilization Method	Terminally sterilized by gamma radiation, 10^{-6} SAL	Terminally sterilized by gamma radiation, 10^{-6} SAL	Identical. Validated sterilization process.
Shelf Life	2 years	1 year	Different: Devices meet the same functional, biological safety and stability standards.
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: Polypropylene & Thermoplastic elastomer with white colorant	Identical barrel, plunger and piston material. Different tip cap material. Devices meet the same biological safety and stability standards.

Device Characteristic	Predicate Device Praxiject™ 0.9% NaCl (K231754)	Subject Device Praxiject™ SP 0.9% NaCl	Comparison Analysis
Syringe Packaging	Sterile Barrier: Plastic heat-sealed peel pouch (printed on one side, clear on the other) – all sizes and fill volumes; OR Aluminum foil heat-sealed pouch (printed on one side) – 10 mL in 10 cc syringe	Dust Cover: Clear plastic heat-sealed flow-wrapped pouch (printed one side with: "Do Not Place Syringe On Sterile Field")	Different. The subject device meets applicable consensus standards for package and device integrity to the point of care.
Content of Syringe Package	One syringe per pouch	One syringe per pouch	Identical.
Dispensing Case and Sterilization/ Shipping Carton Configuration	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 OR 115 syringes per double bag / 4 double bags per shipping carton – only 10mL in 10cc syringe in aluminum foil pouch	30 syringes (10 cc) per cosmetic box; 6 cosmetic boxes per shipping carton	Different. The sterilization process was revalidated for the packaging of the subject devices. Current consensus standards were applied for package and device integrity to the point of care.

Summary of Non-Clinical Testing

The design and manufacturing of the Praxiject™ SP 0.9% NaCl prefilled syringe is subject to risk assessment per ISO 14971 and verification and validation testing in conformance with regulatory guidance and consensus standards applicable to this device type:

Performance Characteristic		Performance Standard	Acceptance Criteria
0.9% Sodium Chloride Solution	Assay	USP Sodium Chloride Injection	0.855 – 0.945% (w/v)
	Identification	USP <191> Sodium and Chloride	Meets USP requirements
	pH	USP <791>	4.5 – 7.0
	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
	Elemental Impurities	USP <232> and USP <233>	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
	Appearance	USP <790> / Visual inspection	Clear and colorless. Free of foreign solid particles.
	Volume	ISO 7886-1, USP <1151>	10.0 - 11.0 mL

Performance Characteristic	Performance Standard	Acceptance Criteria
Sterility	USP <71>	Sterile solution
Sterilization Method Validation	ISO 11137-1, ISO 11137-2, USP <61> (Terminal sterilization by gamma radiation)	SAL 10^{-6}
Shelf-life (Stability)	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
Syringe Design and Container closure integrity	ISO 7886-1, ISO 80369-7 / ISO 594-1 and ISO 594-2 (Adapted solution leakage test)	Conformity to standards and device specifications; Label integrity; Syringe and tip cap seal integrity (no damage, no leakage past piston and tip cap.)
Package integrity	ISO 11607-1, ISO 11607-2, ASTM F1980, ASTM D4169, ISO 7886-1 and ISO 594-2 (Syringe and tip cap integrity verification)	No structural damage to shipping carton; Label integrity; Syringe and tip cap seal integrity (no damage, no leakage past piston and tip cap.)
Biological Safety 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 for the evaluation of 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 device evaluation.

Conclusion

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