December 21, 2017

MedXL Inc.
Premala Premanathan
Regulatory Affairs Associate
Contact Address

Re: K171109
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: November 28, 2017
Received: November 30, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

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.

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

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510(k) Summary K171109

December 20, 2017

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
Submitter/Manufacturer:	MedXL Inc.
Address:	285 Av Labrosse Pointe Claire, Quebec H9R 1A3, Canada Tel: (+1) 514.695.7474 Fax: (+1) 514.695.1511
Contact:	Premala Premanathan, Regulatory Affairs Associate

This 510(k) Summary has been prepared in accordance with 21 CFR §807.92.

Predicate Device

K082837, Excelsior Saline Pre-filled Syringe(s) in Sterile Field Packaging – Excelsior Medical Corp.

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 fill 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 plastic peel pouch and terminally sterilized by gamma irradiation.

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.

Comparison of Technological Characteristics

The Praxiject™ 0.9% NaCl prefilled syringe is substantially equivalent to the predicate device in fundamental technology, product design and materials, operating principles, and performance characteristics for the intended use. The differences between the two devices have been addressed by material and device component qualification, process and packaging validation, and finished product release testing in conformance with recognized consensus standards.

A side-by-side comparison of key device characteristics is presented in the following table.

Device Characteristic	**Predicate Device (K082837)**	**Praxiject™ 0.9% NaCl**
Indications for Use	Excelsior Sterile Field Saline Flush Syringe(s) are intended for use in flushing IV catheters and IV tubing.	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.
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.
Syringe Size and Fill Volumes	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
Fill Volume Graduations	On syringe label	On syringe label
Syringe Content	0.9% Sodium Chloride Injection, USP	0.9% Sodium Chloride Injection, USP
Labeled Non-pyrogenic	Yes	Yes
Single Use Only	Yes	Yes
Sterile	Yes	Yes
Use on Sterile Field	Yes	Yes
Sterilization Method	Terminally sterilized by steam, 10^{-6} SAL	Terminally sterilized by gamma radiation, 10^{-6} SAL
Shelf Life	2 years	2 years
Syringe Material	- Barrel and Plunger: Polypropylene - Plunger: Isoprene rubber (Not made with natural rubber latex) - Tip Cap: Polypropylene with white colorant	- Barrel and Plunger: Polypropylene - Plunger: Bromobutyl rubber (Not made with natural rubber latex) - Tip Cap: ABS with white colorant
Syringe Packaging	Plastic peel pouch (printed on one side, clear on the other)	Plastic peel pouch (printed on one side, clear on the other)
Content of Syringe Package	One or two syringes per pouch	One syringe per pouch

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.

Device / Performance Characteristic	Performance Standard	Results
Solution	Sodium Chloride Injection, USP 39-NF34	Conforms
Plastic syringe	ISO 7886-1, 0 mL average syringe induced reflux	Conforms
Biocompatibility	ISO 10993-1	N/A
- Hemolysis	ISO 10993-4 (ASTM F756)	Non-hemolytic
- Cytotoxicity	ISO 10993-5	Non-cytotoxic
- Sensitization	ISO 10993-10	Non-sensitizer
- Irritation/Intracutaneous reactivity	ISO 10993-10	Non-irritant
- Acute system toxicity	ISO 10993-11	No systemic toxicity
- Material–mediated pyrogenity	ISO 10993-11 (USP <151>)	No material mediated response observed
- Bacterial Endotoxins	USP <85> and USP <161> (≤ 0.5 EU/mL)	Conforms
- Chemical characterization	ISO 10993-18	Acceptable extractables/leachables profile
- Particulate matter	USP <788>	Conforms

The shelf life of the final finished sterilized device was evaluated using the recognized consensus standard on the requirements for materials, sterile barrier systems and packaging systems for terminally sterilized medical devices (ISO 11607-1).

Substantial Equivalence Conclusion

The results of the above described non-clinical testing demonstrate that the Praxiject™ 0.9% NaCl prefilled syringe fulfills the established performance criteria and it is substantially equivalent to the predicate device.