July 20, 2022

Pentaferte Italia S.r.l.
% Luca Giustini
US Country Manager and Partner
Pqe Us
12300 Twinbrook Parkway, Suite 400 4th Floor
Rockville, Maryland 20852

Re: K214080
Trade/Device Name: Pentaflush
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular catheter
Regulatory Class: Class II
Product Code: NGT
Dated: June 6, 2022
Received: June 13, 2022

Dear Luca Giustini:

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,

Clarence W. Murray, III, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214080

Device Name
PentaFlush

Indications for Use *(Describe)*
Pentaflush saline 0.9% NaCl prefilled syringe is intended only for flushing in situ vascular access devices.
May be placed on a sterile field.
Pentaflush saline 0.9% NaCl prefilled syringe is intended for single patient and single use only.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

K214080

July 19, 2022

Device Trade Name:	PentaFlush
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:	Pentaferte Italia srl
Address:	Viale Piane Nocella, 23 – 64012 Campli (TE) – Italy
Tel:	+39.0861.560201
Fax:	+39.0861.560200
Contact Name:	Rosa di Gioia, Quality and Regulatory Manager

Predicate Device and Reference Device

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

Reference Device:	0.9% Sodium Chloride I.V. Flush Syringe for Sterile Delivery
510(k) Number	K 201286
Classification:	Class II, 21 CFR §880.5200, Saline, Vascular Access Flush
Product Code:	NGT

Device description

The PentaFlush saline 0.9% NaCl prefilled syringe is a single-use device intended only for flushing in-situ vascular access devices. It is a polypropylene syringe containing an isotonic solution of sterile and non-pyrogenic 0.9% sodium chloride solution. These are ready for use devices that can be placed on sterile field.

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Sede legale e stabilimento: Viale Piane Nocella, 23 - 64012 Campli (TE) – Italy - **PEC:** pentaferteitalia@legalmail.it
Uffici commerciali e amministrazione: Via Modena, 119 - 44122 Ferrara, Italy - **Tel:** + 39 0532 778811 - **Fax:** +39 0532 778812

The product is available in volumes of 3ml, 5ml and 10ml of saline solution in 10 ml syringes, which has a larger diameter in order to avoid that, with the same force applied on the shaft button, the higher pressure generated in the 3ml and 5ml capacities may cause the vascular catheter to rupture. What differentiates the three versions is the graduated scale, whose maximum capacity coincides with the nominal capacity of each version (3ml, 5ml and 10ml).

In all capacities Luer Lock connector of the barrel is closed with a cap.

The barrel is filled with a 0.9% NaCl isotonic solution, sterile, pyrogen-free, up to the nominal capacity of the scale; an acitotoxic synthetic rubber piston is assembled to the polypropylene plunger, whose fiducial line is positioned at the nominal capacity of the syringe.

The primary packaging of PentaFlush pre-filled syringes can be in:

a) a blister of medical paper and PE/PE peel, or
b) an aluminum pouch of PET/ALL/PE peel.

PentaFlush saline 0.9% NaCl prefilled syringes are used only by healthcare professionals, is intended for single patient and single use only.

Does not contain preservatives. Not made with natural rubber latex.

Rx Only.

Technological characteristics compared to the predicate device

The subject device has the same intended use, flushing vascular access, and uses the same technology.

Technical characteristics are the same: prefilled plastic piston syringes with Luer lock connection filled with 0.9% Sodium Chloride Injection solution, in the same syringe size and fill volumes.

The differences:

- the predicate device has also 5 cc syringes;
- the 0.9% Sodium Chloride Injection solution is compliant with EU Ph. (showed compliance to USP as well) in the subject device and with the USP in the predicate device;
- the shelf life of the subject device is 3 years, while the shelf life of the predicate device is 2 years;
- the piston material, made of synthetic isoprene in the subject device and in bromobutyl rubber in the predicate device. The synthetic isoprene, however, is the same material used for the piston of the reference device K201286;
- the packaging materials: paper/plastic film vs. plastic film and multi-layer peel vs. aluminium foil for the subject device and the predicate device respectively are all these materials widely employed for such kind of applications;
- the number of syringes per case

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

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Device Characteristic	Subject Device PentaFlush saline prefilled syringe (K214080)	Predicate Device Praxiject™ 0.9% NaCl (K192414)	Comparison
Indications for Use [Intended Use]	PentaFlush 0.9% NaCl prefilled syringe is intended only for flushing in situ vascular access devices. May be placed on a sterile field. PentaFlush 0.9% NaCl prefilled syringe is intended for single patient and single use only.	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.	Same
Design	Prefilled plastic piston syringe with Luer lock connection fitting and nonvented, female Luer lock tip cap.	Prefilled plastic piston syringe with Luer lock connection fitting and nonvented, female Luer lock tip cap.	Same
Syringe Size and Fill Volumes	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	Not relevant differences: same volumes 3, 5 and 10 ml in 10 cc syringes. The predicate device has also 5 cc syringes.
Fill Volume Graduations	On syringe label	On syringe label	Same
Syringe Content	0.9% Sodium Chloride Injection	0.9% Sodium Chloride Injection, USP	Similar Same solution 0.9% Sodium Chloride; subject device is compliant with EU Ph and showed compliance to USP as well, predicate device with USP.
Labeled Non-pyrogenic	Yes	Yes	Same
Single Use Only	Yes	Yes	Same
Sterile	Yes	Yes	Same

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Device Characteristic	Subject Device PentaFlush saline prefilled syringe (K214080)	Predicate Device Praxiject™ 0.9% NaCl (K192414)	Comparison
Use on Sterile Field	Yes	Yes	Same
Sterilization Method	Terminally sterilized by gamma radiation, 10^{-6} SAL	Terminally sterilized by gamma radiation, 10^{-6} SAL	Same
Shelf Life	3 years	2 years	Different The shelf life of the subject device is 3 years, while the shelf life of the predicate device is 2 years.
Syringe Material	–Barrel: Polypropylene –Plunger: Polypropylene –Piston: Synthetic isoprene (not made with natural rubber latex) Tip Cap: ABS with white colorant	–Barrel: Polypropylene –Plunger: Polypropylene –Piston: Bromobutyl rubber (not made with natural rubber latex) Tip Cap: ABS with white colorant	Similar Same materials for barrel, plunger and tip cap. The piston is different: it is made of synthetic isoprene in the subject device and in bromobutyl rubber in the predicate device. However, the synthetic isoprene is the same material used for the piston of the reference device K201286.

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Device Characteristic	Subject Device PentaFlush saline prefilled syringe (K214080)	Predicate Device Praxiject™ 0.9% NaCl (K192414)	Comparison
Syringe Packaging	HL60 PAPER + PET/PE Peel (printed on one side, clear on the other) – all sizes and fill volumes OR PET12/ALL9/PE50 Peel (printed on one side) – 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	Similar Both the devices have two different types of packaging of the same design. The materials are different: paper/plastic film vs. plastic film and multi-layer peel vs. aluminum foil for the subject device and the predicate device respectively. However, all these materials are widely employed for such kind of applications .
Content of Syringe Package	One syringe per pouch	One syringe per pouch	Same
Shipping Package Configuration	30 syringes (3, 5, 10 ml) per case 4 cases per shipping carton – all sizes, fill volumes and syringe packaging	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 number of syringes per case is different.

The subject device has the same intended use and the same technical characteristics as the predicate device.

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Summary of Non-clinical Testing

The non-clinical tests performed on PentaFlush saline 0.9% NaCl prefilled syringe demonstrate the conformance of the subject device to the applicable standard as shown below:

Test	Standards	Acceptance Criteria	Results
Mechanical Testing/Stability			
Visual inspection of pouch seals	ASTM F1886/F1886M-16	No defect of the integrity of seals must be found	Conforms
Bubble emission test of pouch	EN 868-5 Annex C	No leaks	Conforms
Visual inspection of prefilled syringe for damage	ISO 7886-1	No damage, no leak (consistent with instructions for use)	Conforms
Test for liquid leakage and resistance of luer lock fitting	EN ISO 80369-7	No leaks; no cracks	Conforms
Test for integrity of printed label	ASTM F2250	Print must remain defined and legible, color must not lighten, ink must not run	Conforms
Distribution cycle (Transport)	ASTM D4169 Distribution Cycle 13 Packaging integrity ISO 11607-1	The integrity of the packaging must be preserved	Conforms
Chemical Testing			
Assay of Sodium Chloride	USP monograph	0.855 to 0.945% NaCl	Conforms
pH	USP<791>	4.5 to 7.0	Conforms
Identification of Sodium and Chloride	USP <191>	Successful identification	Conforms
Sub-visible particulate matter	USP <788>	≥ 10µm: ≤6000 part/syringe ≥ 25µm: ≤ 600 part/syringe	Conforms
Elemental Impurities (Heavy Metals)	USP <232>/<233>	Arsenic: ≤ 1.5µg/g Cadmium: ≤ 0.2µg/g Mercury: ≤ 0.3µg/g Lead: ≤ 0.5µg/g	Conforms
Iron	USP <24>	Iron: ≤ 2ppm	Conforms

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Sterilization			
Bacterial Endotoxins	USP <85>	≤ 0.5 EU/mL	Conforms
Sterilization Validation	ISO 11137-2	10^{-6} SAL	Conforms
Biocompatibility			
Cytotoxicity	ISO 10993-5	Non-cytotoxic	Conforms
Skin-sensitization	ISO 10993-10	Non-sensitizer	Conforms
Intracutaneous Reactivity	ISO 10993-10	Non-irritant	Conforms
Acute systemic toxicity	ISO 10993-11	No systemic toxicity	Conforms
Pyrogenicity (material-mediated)	ISO 10993-11 (USP <151>)	No material mediated response observed	Conforms
Hemolysis	ISO 10993-4 (ASTM F756-17)	Non-hemolytic	Conforms
Tests for interaction with blood	ISO 10993-4	No interaction with blood	Conforms

Conclusion

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

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