May 31, 2024

Smiths Medical ASD, Inc.
Benjamin Rappaport
Regulatory Affairs Specialist
6000 Nathan Lane North
Minneapolis, Minnesota 55442

Re: K232943
Trade/Device Name: Hypodermic Needle-Pro® EDGE™ Safety Device with Low Dead Space Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QNQ, FMI, MEG,
Dated: April 30, 2024
Received: May 1, 2024

Dear Benjamin Rappaport:

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,

Shruti N. Mistry -S 2024.05.31 15:07:21 -04'00'

Shruti Mistry
Assistant Director
Division of Drug Delivery and General
Hospital Devices, and Human Factors
Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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)*
K232943

Device Name
Hypodermic Needle-Pro® EDGE™ Safety Device with Low Dead Space Syringe

Indications for Use *(Describe)*
This device is intended for use to inject fluids into or withdraw fluids from the body. The needle protection device covers the needle after use to help prevent needle sticks.

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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K232943-510(k) Summary

Date Prepared

April 30, 2024

a. Device Information

Device Names	Hypodermic Needle-Pro® EDGE™ Safety Device with Low Dead Space Syringe

b. Manufacturer Information

Applicant, 510(k) owner	Smiths Medical ASD, Inc. 6000 Nathan Lane North Minneapolis, MN 55442 Establishment Registration: 3012307300
Contact Person	Benjamin Rappaport Regulatory Affairs Associate II 6000 Nathan Lane North Minneapolis, MN 55442 Telephone: (763) 383-3000

c. Device Classification and Number

Name of the Devices:	Hypodermic Needle-Pro® EDGE™ Safety Device with Low Dead Space Syringe
Common or Usual Names:	Sterile Low Dead Space Piston Syringe, Needle, Hypodermic
Classification:	II
Regulation Numbers and Names:	21CFR880.5860 – Piston syringe 21CFR880.5570 – Hypodermic Single Lumen Needles
510(k) Review Panels:	General Hospital
Product Codes:	QNQ, FMI, MEG

d. Predicate Devices Information

K211634	Hypodermic Needle-Pro® EDGE™ Safety Device (Smiths Medical ASD, Inc.)

e. Indications for Use

This device is intended for use to inject fluids into or withdraw fluids from the body. The needle protection device covers the needle after use to help prevent needle sticks.

f. Device Description

The Hypodermic Needle-Pro® EDGE™ Safety Device with Syringe is intended for injection or aspiration of fluids using a Luer lock (LL) or Luer slip syringe. The device is provided sterile and is for single use only. The Hypodermic Needle-Pro® EDGE™ Safety Device with Syringe is an extension of Smiths Medical's Hypodermic Needle-Pro® EDGE™ product portfolio. The Low Dead-Space (LD) Syringe – new component – is added to form new device combo with the previously cleared Hypodermic Needle-Pro® EDGE™ Safety Device. The device combo is intended to offer an optimization of the volume of fluids injected to patients, and thus reduce the amount of medical product remaining in the needle and the syringe's hub after injection.

The Needle-Protection (Needle-Pro) EDGE™ safety device covers the needle after use to help prevent needle sticks. The device features a *one-piece* design of polypropylene needle hub and protective sheath with a living hinge. The stainless-steel needle cannula is permanently affixed into the hub. After a procedure is completed, the needle is pressed into the sheath using a one-handed technique and the needle is contained within the sheath.

The Low Dead-Space (LD) Syringe is a new component to be used along with the Hypodermic Needle-Pro® EDGE™ Safety Device. The LD Syringe is designed with luer lock (LL) connection to provide a secure and leak-free connection between the syringe and the needle and maintain a continuous lumen for fluid flow. The LD Syringe plunger is designed for less product waste without changing the use of the device. The Syringe plunger tip extends into the syringe neck reducing fluid waste. The fluid waste is about 0.010 mL (10 µL), max = 0.015 mL (15 µL) for the LD syringe.

g. Technological Characteristics Compared to Predicate Device

The Hypodermic Needle-Pro® EDGE™ Safety Device with Syringe is substantially equivalent in performance, indication, design, and materials to the current Hypodermic Needle-Pro® EDGE™ Safety Device with Syringe, cleared under Premarket notification K211634.

The introduction of the proposed configuration has modified the existing syringe by lengthening 0.043". The physical characteristics differ in the materials used, which are addressed through biocompatibility testing per ISO 10993-1:2018. The differences are in comparison with the predicate: Hypodermic Needle-Pro® EDGE™ Safety Device with Syringe.

Device Comparison Table

Characteristic	**Predicate Device – K211634** **Hypodermic Needle-Pro® EDGE™ Safety Device with Syringe**	**Subject Device** **Hypodermic Needle-Pro® EDGE™ Safety Device with Syringe**	**Comparison**
General			

Characteristic	Predicate Device – K211634 Hypodermic Needle-Pro® EDGE™ Safety Device with Syringe	Subject Device Hypodermic Needle-Pro® EDGE™ Safety Device with Syringe	Comparison
Indications for Use	The device is intended for use to inject fluids or withdraw fluids from the body. The needle protection device covers the needle after use to help prevent needle sticks.	The device is intended for use to inject fluids or withdraw fluids from the body. The needle protection device covers the needle after use to help prevent needle sticks.	Same
Single Use	Yes	Yes	Same
Prescription	Yes	Yes	Same
Packaging	Form Fill Seal, Coated Paper "top web"/polyethylene- nylon coextrusion "bottom web"	Form Fill Seal, Coated Paper "top web"/polyethylene- nylon coextrusion "bottom web"	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Hypodermic Needle-Pro® EDGE™ Safety Device			
Safety Feature (Active or Passive)	Active	Active	Same
On-handed Safety Activation	Yes	Yes	Same
Hinge Style Safety Feature	Yes	Yes	Same
Needle Permanently attached to the Needle-Protection	Yes	Yes	Same
Color Code to Reflect Needle Gauge Size	Yes, for needle hub and protective sheath	Yes, for needle hub and protective sheath	Same
Safety Feature as Integral part of the Hypodermic Needle	Yes	Yes	Same
Needle Gauge X Length *(Available on the finished goods. See also **Combo** below)*	18G X 1" 19G X 1" 20G X 1" 21G X 1" 22G X 1" 23G X 1" 25G X 1" 27G X ½" 18G X 1 ½" 19G X 1 ½" 20G X 1 ½" 21G X 1 ½" 22G X 1 ½" 23G X 1 ½" 25G X 5/8"	- - - - - - 25G X 1" - - - - - - 23G X 1 ½" 25G X 5/8"	Matching configurations
Needle Material	304 SS cannula	304 SS cannula	Same
Syringe			
Syringe Size – 1mL	x	x	Matching configurations
Syringe Size – 3mL	x	x	
Syringe Size – 5mL	x	-	

<table>
<tr><th colspan="2" rowspan="2">Characteristic</th><th>Predicate Device – K211634</th><th>Subject Device</th><th rowspan="2">Comparison</th></tr>
<tr><th>Hypodermic Needle-Pro® EDGE™ Safety Device with Syringe</th><th>Hypodermic Needle-Pro® EDGE™ Safety Device with Syringe</th></tr>
<tr><td></td><td>10mL</td><td>x</td><td>-</td><td></td></tr>
<tr><td rowspan="2">Syringe Length</td><td>1mL</td><td>5.888” ± 0.005”
with Needle Pro EDGE Long
~ 3.767”
without Needle Pro EDGE Long</td><td>3.724” ± 0.005” (94.6 mm)
without Needle Pro EDGE Long</td><td rowspan="2">Slight difference between the predicate device syringe and proposed subject device about 0.043” (1.1 mm).</td></tr>
<tr><td>3mL</td><td>5.510” ± 0.005”
with Needle Pro EDGE Long
~ 3.388”
without Needle Pro EDGE Long</td><td>3.346” ± 0.005” (85 mm)
without Needle Pro EDGE Long</td></tr>
<tr><td rowspan="4">Syringe Assembly Material</td><td>Gasket</td><td>Elastomer resin</td><td>IR rubber</td><td rowspan="4">Material differences were addressed through biocompatibility testing per ISO 10993-1:2018.</td></tr>
<tr><td>Plunger</td><td>Polypropylene</td><td>Polypropylene</td></tr>
<tr><td>Barrel</td><td>Polypropylene</td><td>Polypropylene</td></tr>
<tr><td>Lubricant</td><td>Silicone</td><td>Silicone</td></tr>
<tr><td colspan="2">Luer Lock</td><td>Yes</td><td>Yes</td><td rowspan="2">Same</td></tr>
<tr><td colspan="2">Luer Compliance</td><td>ISO 594-1 and 594-2</td><td>ISO 80369-7</td></tr>
<tr><td colspan="2">Dead Space Specification</td><td>Standard Dead Space
~ 0.070mL of fluid waste</td><td>Low Dead Space
~ 0.010mL of fluid waste
Max: ≤ 0.015mL</td><td>Lower fluid waste with the subject device</td></tr>
<tr><td colspan="5">Finished Good: Needle + Syringe Combo</td></tr>
<tr><td colspan="2">Combo Configuration

(Syringe, Needle Gauge X Length)</td><td>1mL, 25G X 1”
1mL, 27G X ½”
3mL, 18G X 1”
3mL, 19G X 1”
3mL, 20G X 1”
3mL, 21G X 1”
3mL, 22G X 1”
3mL, 23G X 1”
3mL, 25G X 1”
5mL, 20G X 1”

10mL, 20G X 1”</td><td>1mL, 23G X 1 ½”
1mL, 25G X 5/8”

3mL, 18G X 1 ½”
3mL, 19G X 1 ½”
3mL, 20G X 1 ½”
3mL, 21G X 1 ½”
3mL, 22G X 1 ½”
3mL, 23G X 1 ½”
3mL, 25G X 5/8”

5mL, 21G X 1 ½”
10mL, 20G X 1 ½”
10mL, 21G X 1 ½”</td><td>1mL, 23G X 1 ½”
1mL, 25G X 1”
-
-
-
-
-
-
3mL, 25G X 1”
-

-</td><td>1mL, 25G X 5/8”

-
-
-
-
-
3mL, 23G X 1 ½”
-

-
-
-</td><td>Matching configurations</td></tr>
<tr><td colspan="5">Note: Symbol “x”: available as part of the device combo
Symbol “-“: not available on the subject device combo</td></tr>
</table>

h. <u>Performance Data</u>

Biocompatibility Testing was performed per ISO 10993-1:2018.

Sterilization testing was performed per ISO 11135:2014 and AAMI TIR28:2016.

Shelf-Life testing was performed per ISO 11607:2019.

Non-Clinical Bench Verification Testing was performed per ISO 80369-1:2018 and ISO 7886-1:2017.

The subject device was adopted into the following non-clinical bench verification testing of the predicate device: ISO 7864:2016, ISO 23908:2011, ISO 9626:2016.

All performance testing was conducted according to the applicable ISO standards and met all pre-defined acceptance criteria. As such, the subject device is substantially equivalent to the predicate device.

i. Conclusion

The subject device has the same intended use and indications for use as the predicate. The subject device has the same characteristics and principles of operation. The differences between devices are demonstrated through device non-clinical bench testing. The subject device is substantially equivalent to the predicate device.