August 26, 2021

Smiths Medical ASD, Inc.
Adam Johnson
Director, Global Regulatory & Quality Systems
6000 Nathan Lane North
Minneapolis, Minnesota 55442

Re: K211634
Trade/Device Name: Hypodermic Needle-Pro EDGE Safety Device
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI, FMF
Dated: July 28, 2021
Received: July 30, 2021

Dear Adam Johnson:

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,

CAPT Alan Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211634

Device Name
Hypodermic Needle-Pro® EDGE™ Safety Device

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
K211634

a. Device Name
Hypodermic Needle-Pro® EDGE™ Safety Device

Common Name
Hypodermic Syringe

b. Manufacturer Information

Applicant, 510(k) Owner
Smiths Medical ASD, Inc.
6000 Nathan Lane North
Minneapolis, MN 55442
Establishment Registration: 3012307300

Name of Contact Person
Dominique E. Neisz
Senior Regulatory Affairs Specialist
6000 Nathan Lane North
Minneapolis, MN 55442
Telephone: 763-383-3000

Date Prepared
August 26, 2021

c. Device Classification and Number
Name of Device: Hypodermic Needle-Pro® EDGE™ Safety Device with Syringe
Common or Usual Name: Needle, hypodermic, single lumen
Classification: II

Classification Regulation Number & Name:
880.5570 (Hypodermic Single Lumen Needles) &
880.5860 (Piston Syringes) Panel: 80, General
Hospital Product Code: FMI & FMF & MEG

d. Predicate Device Information
K071785 (Smiths Medical ASD, Inc.) Hypodermic Needle-Pro® EDGE™ Safety Device and EDGE™ Safety Device with Syringe. The Hypodermic Needle-Pro® EDGE™ Safety Device with Syringe is substantially equivalent in performance, indications, design, and materials to the Hypodermic Needle-Pro® EDGE™ Safety Device, cleared under Premarket notification # K071785.

e. Device Description

Subject Device: The Hypodermic Needle-Pro® EDGE™ Safety Device with Syringe is intended for injection or aspiration of fluids using a Luer lock or Luer slip syringe. The Needle-Protection 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. The sheath has an “arrow” indicating the bevel orientation, i.e. when the sheath is oriented to the right, the bevel

is in the “up position.” After the procedure is completed, the needle is pressed into the sheath using a one-handed technique. As the needle enters the protective sheath, the lugs on the needle hub snap into the clips of the protective sheath resulting in a “bottom snap” and the needle is contained within the sheath. In addition to the “bottom snap,” the Needle-Protection sheath has 2 retaining hooks. The EDGE™ safety device may be removed from the syringe when required by a specific medical procedure, i.e., the EDGE™ safety device may be removed from a blood sampling syringe to process the blood sample. The EDGE™ safety device is then discarded into a sharps container. The Subject device is comprised of a 1mL Luer lock syringe with a 23G x 1.5in needle/cannula. This configuration is not currently offered within the Smiths Medical portfolio of Hypodermic Needle-Pro® EDGE™ with syringe devices.

The Subject Needle-Pro® EDGE™ Safety Device with Syringe is offered in the following configurations.

Syringe Size (mL) Luer Lock	**1mL**
Needle Gauge (G) and Length (in)	**23G x 1 ½”**

Indications for Use of the Device: 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.

Technological Characteristics Compared to Predicate Device: Hypodermic Needle injection or aspiration therapies are commonly performed clinical practices, intended to either deliver a measured dosage of a medicinal product, or to obtain patient fluids from below the surface of the skin. This application is consistent in both the predicate and subject devices. The Hypodermic Needle-Pro® EDGE™ Safety Device is substantially equivalent in performance, indication, design, and materials to the current Hypodermic Needle-Pro® EDGE™ Safety Device, cleared under Premarket notification K071785 as summarized by the key technological characteristics listed below.

- Stainless Steel Cannula - used to puncture the patient’s skin and act as a sterile fluid path.
- Polypropylene Syringe – primary operating mechanism for either the delivery or aspiration of fluids.
- Needle Hub/Protection Sheath – primary operating mechanism for sharps safety and needle stick protection.

The introduction of the Subject device has not modified the existing technologies or physical characteristics of device components compared to the predicate Hypodermic Needle-Pro® EDGE™ Safety Device. The Subject device configuration presents the following differences from the predicate device.

- 1mL Polypropylene Syringe combined with 1 1/2 in 23G Needle – The constituent components (Hub and Needle) are offered in other configurations but not together as found in the Subject device.

A comprehensive comparison of the Subject device to the predicate device is provided in Table 3.

Table 3: Predicate Device Comparison:

Characteristic	Predicate Device – Hypodermic Needle-Pro® EDGE™ Safety Device with Syringe: K071785	Subject Device – Hypodermic Needle-Pro® EDGE™ Safety Device with Syringe: K211634
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.	Same
Sterilization Method	EtO	Same
Single Use	Yes	Same
Prescription	Yes	Same
Packaging	Form Fill Seal, Coated Paper "top web"/polyethylene-nylon coextrusion "bottom web"	Same
Safety Feature (Active or Passive)	Active	Same
On-handed safety activation	Yes	Same
Hinge Style safety feature	Yes	Same
Needle is permanently attached to the Needle-Protection	Yes	Same
Color Code reflects needle gauge size	Yes, for needle hub and protective sheath	Same
Safety feature is supplied as an integral part of the hypodermic needle	Yes	Same

Components					
Device Configuration Syringe and Needle Gauge X Length	1mL	3mL	5mL	10mL	Same, with the addition of a configuration that includes a 1mL Luer lock syringe and 23G X 1 ½" needle

	25G X 1” 25G X 5/8” 27G X ½”	18G X 1” 18G X 1 ½” 19G x 1” 19G X 1 ½” 20G x 1” 20G X 1 ½” 21G X 1” 21G X 1 ½” 22G X 1” 22G X 1 ½” 23G X 1” 23G X 1 ½” 25G X 1” 25G X 5/8”	20G X 1” 21G X 1 ½”	20G X 1” 20G X 1 ½” 21G X 1 ½”	
Needle Hub/Needle-Protection Sheath	“One-piece” design with “bottom snap”, no dead space is added by protective sheath				Same
Materials					
Needle	304 SS cannula				Same
Protection Sheath/Hub	“one piece” polypropylene hub/protective sheath with respective gauge size colorant, UV cured adhesive, silicone lubricant				Same

f. Performance Data: The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing
Biocompatibility testing was leveraged from the predicate submission.

Sterilization
The Hypodermic Needle-Pro® EDGE™ Safety Device is sterilized by ethylene oxide according to the same method as the predicate device.

To confirm the changes to the Subject device automation parameters do not impact the sterility of the device a Microbiology Product Adoption was performed in accordance with AAMI TIR28:2016. The Microbiology Product Adoption confirmed the Subject device is similar in componentry, packaging and complexity as all other Hypodermic needles currently manufactured at the Smiths Medical Keene, NH site, and the Subject device will not have an adverse effect on the currently validated Ethylene Oxide sterilization performed. No new sterilization validation is required to use the Subject device with the existing validated Sterilization process.

Shelf Life
Shelf-Life Verification studies were conducted at T=0 and T=2 under accelerated aging conditions to verify that the claimed shelf life of 2 years is supported. There were no failures identified indicating the claimed expiration date is supported.

Non-Clinical Bench Verification Testing
Device specific non-clinical bench testing was performed in accordance with the pertinent FDA consensus standards. The performance and design testing conducted serve as the primary means for establishing substantial equivalence, the testing included the following:

- ISO 7886-1:2017 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
- ISO 7864:2016 Sterile hypodermic needles for single use - Requirements and test methods
- ISO 594-2:1998 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings
- ISO 23908:2011 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
- ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- ISO 6009:2016 Hypodermic needles for single use - Colour coding for identification

The compatibility of the Needle Hub/Safety Sheath and the Hypodermic Syringe was considered the technological characteristic which introduced the greatest risk of the Subject device. Potential incompatibility issues may result in misconnection, and consequently leakage, delay in therapy, or repeated procedures to ensure patients receive appropriate dosages. Compliance to ISO 594-2 for Luers found on the Needle Hub/Safety Sheath and Hypodermic Syringe serve as the risk mitigations to the aforementioned safety concerns.
The remaining standards applied for performance and design evaluation are derived from the recommended consensus standards by product code and the predicate submission.

Clinical Studies
Clinical studies were not deemed necessary to support the substantial equivalence decision. The device technologies in the subject device are equivalent to the predicate device. Additionally, the Subject device is not being introduced to cater to a new set of clinical indications or environments which may require additional clinical feedback to support the basis for substantial equivalence.

Conclusion
The non-clinical data received through the biocompatibility, sterilization, shelf-life, performance, and design testing provide the required information to support substantial equivalence. Results of the testing conducted, demonstrate the Subject device will perform as intended for the identified indications.
Based on the comparison and analysis above, the Subject device is determined to be Substantially Equivalent (SE) to the predicate devices.