Smiths Medical ASD, Inc.
Sunita Teekasingh
Senior Principal Regulatory Affairs Specialist
Vascular Access and Infusion Regulatory Affairs Interim Manager
6000 Nathan Lane North
Minneapolis, Minnesota 55442

Re: K172800
Trade/Device Name: Portex® Lancet Point Spinal Needles with NRFit™ connectors
Portex® Pencil Point Spinal Needles with NRFit™ connectors
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: MIA
Dated: May 11, 2018
Received: May 15, 2018

Dear Sunita Teekasingh:

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 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,

Todd D. Courtney -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)*
K172800

Device Name

Portex® Lancet Point Spinal Needles with NRFit™ connectors
Portex® Pencil Point Spinal Needles with NRFit™ connectors

Indications for Use *(Describe)*

The Portex® Lancet Point Spinal Needles with NRFit™ connectors are indicated for the injection of local anesthetics or narcotics to provide regional anesthesia or withdrawal of cerebrospinal fluid when used with compatible components. The intended target population is pediatrics and adults.

The Portex® Pencil Point Spinal Needles with NRFit™ connectors are indicated for the injection of local anesthetics or narcotics to provide regional anesthesia or withdrawal of cerebrospinal fluid when used with compatible components. The intended target population is pediatrics and adults.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

smiths medical
bringing technology to life

1. ADMINISTRATIVE INFORMATION

510(k)	K172800
Applicant's Name And Address	Smiths Medical ASD, Inc. 6000 Nathan Lane North Minneapolis, MN 55442 USA
Contact Person	Sunita Teekasingh Senior Principal Regulatory Specialist Vascular Access and Infusion Regulatory Affairs Interim Manager Phone: 763-383-3336 Fax: 763-383-3679 Email: sunny.teekasingh@smiths-medical.com
Date	June 8, 2018
Regulation No.	21 CFR 868.5150
Regulation Name	Anesthesia conduction needle
Primary Product Codes	MIA
Classification	Class II
Trade Name	PORTEX® Lancet Point Spinal Needles with NRFit™ connectors PORTEX® Pencil Point Spinal Needles with NRFit™ connectors

2. REASON FOR SUBMISSION

The purpose of this submission is to make a modification to the currently marketed Smiths Medical PORTEX® Spinal Anesthesia Needles and Introducer Needles, which are being updated to include an ISO 80369-6 compliant connector for neuraxial applications.

3. DEVICE INFORMATION

	Predicate Device	**Subject Devices**
Trade Name(s)	PORTEX® Spinal Anesthesia Needles and Introducer Needles	PORTEX® NRFit™ Spinal Lancet Point Needles PORTEX® NRFit™ Spinal Pencil Point Needles
Regulation No.	21CFR868.5150	21CFR868.5150
Regulation Name	Anesthesia conduction needle	Anesthesia conduction needle
Regulatory Class	II	II
Product Code	MIA	MIA
510(k)	K983858	K172800

Reference device - K112515 – Pencan Spinal Needles, Spinocan Spinal Needles, Spinal Introducer Needles. This is used to support the expansion of the indication of withdrawal of cerebrospinal fluid.

4. DEVICE DESCRIPTION

The PORTEX® Lancet Point Spinal Needle with NRFit™ connectors and PORTEX® Pencil Point Spinal Needles with NRFit™ connectors are indicated for the injection of local anesthetics or narcotics to provide regional anesthesia or withdrawal of cerebrospinal fluid when used with compatible components. The intended target population is pediatrics and adults.

The NRFit™ connectors conform to ISO 80369-6, Small bore connectors for liquids and gases in healthcare applications -- Part 6: Connectors for neuraxial applications. The connectors are not compatible with standard luer connectors which is intended to reduce the risk of misconnection that may result in the infusion of medications not intended for neuraxial or regional anesthetic use.

The PORTEX® NRFit™ Spinal Needles are color-coded yellow to indicate medication intended

for neuraxial or regional anesthetic delivery.

This Premarket Notification Traditional 510(k) includes various configurations of PORTEX® Lancet Point with NRFit ™ connectors and PORTEX® Pencil Point Spinal with NRFit ™ connectors. Descriptions of the configurations are provided in the table below.

Device Type	Description
PORTEX® Lancet Point Spinal Needles with NRFit connectors	The PORTEX® Spinal Lancet Point Needle with NRFit™ connectors are a range of sterile, single use needles, and are for the injection of local anesthetics to provide regional anesthesia or withdrawal of cerebrospinal fluid when used with compatible components. The intended target population is pediatrics and adults.
PORTEX® Pencil Point Needles with NRFit™ connectors	The PORTEX® Spinal Pencil Point Needle with NRFit™ connectors are a range of sterile, single use needles, and are for the injection of local anesthetics to provide regional anesthesia or withdrawal of cerebrospinal fluid when used with compatible components. The intended target population is pediatrics and adults.

5. INDICATIONS FOR USE

Device Type	Description
PORTEX® Lancet Point Spinal Needles with NRFit connectors	The Portex® Lancet Point Spinal Needles with NRFit™ connectors are indicated for the injection of local anesthetics or narcotics to provide regional anesthesia or withdrawal of cerebrospinal fluid when used with compatible components. The intended target population is pediatrics and adults.
PORTEX® Pencil Point Needles with NRFit™ connectors	The Portex® Pencil Point Spinal Needles with NRFit™ connectors are indicated for the injection of local anesthetics or narcotics to provide regional anesthesia or withdrawal of cerebrospinal fluid when used with compatible components. The intended target population is pediatrics and adults.

6. SUBSTANTIAL EQUIVALENCE DISCUSSION

The Smiths Medical PORTEX® Lancet Point with NRFit ™ connectors and PORTEX® Pencil Point Spinal with NRFit ™ connectors have the same technological characteristics as the predicate devices with the exception of the NRFit TM Connectors.

The Smiths Medical PORTEX® Lancet Point with NRFit ™ connectors and PORTEX® Pencil Point Spinal with NRFit ™ connectors and predicate devices are both designed for the injection of local anesthetics and provide regional anesthesia. They are both made of the same materials, have the same chemical composition, and have the same design features excluding the NRFit TM connector design.

Differences in connector are addressed by ISO 80369-6, intending to reduce risk of misconnections by updating from luer to NRFit™ connectors. Needle gauge of subject device includes a 27 gauge needle in addition to the range of the predicate. Needle length range of the subject device is 38-152 mm and is within a similar range of the predicate device of 50.8-152.4 mm, being 12.8 mm shorter than the predicate. Potential risks associated with the length and gauge differences are addressed through biocompatibility and bench testing and validation and verification data. The differences are not critical to the intended therapeutic use of the device and do not raise different questions of safety and effectiveness of the device when used as labeled.

A comparative analysis is provided in **Table 1**.

Table 1: PORTEX® NRFit™ Spinal Needles

Characteristic	Predicate Device K983858	Subject Device	Discussion
Company	Sims Portex® (Smiths Medical)	Smiths Medical	N/A
FDA Product Code & CFR	MIA 21 CFR 868.5150	MIA 21 CFR 868.5150	Same
Regulation Name	Anesthesia conduction needle	Anesthesia conduction needle	Same
Regulatory	II	II	Same
Trade Name(s)	PORTEX® Spinal Anesthesia Needles and Introducer Needles	PORTEX® NRFit™ Spinal Lancet Point Needles PORTEX® NRFit™ Spinal Pencil Point Needles	N/A
Common Name	Spinal Anesthesia Needles	Spinal Anesthesia Needles	Same
Indications for Use	Spinal needles are indicated for the **injection of local anesthetics** into a patient **to provide regional anesthesia**.	The Portex® Lancet Point and Pencil Point Spinal Needles with NRFit™ connectors are indicated for the injection of local anesthetics or narcotics to provide regional anesthesia or withdrawal of cerebrospinal fluid when used with compatible components. The intended target population is pediatrics and adults.	Similar. Both the subject and predicate device are indicated for the injection of local anesthetics, and to provide regional anesthesia. The introduction of the spinal needles with the NRFit connectors into the intrathecal space does not alter the safety profile of the subject devices. Both the subject and predicate devices can be used for collection of cerebral spinal fluids. The addition of the NRFit connector does not impact the safety profile when compared to the predicate device. The addition of the narcotics is an extension of regional anesthesia administration procedures, therefore the safety profile remains the same. The NRFit connection is a safety feature that aids in prevention of inadvertent misconnections.

Indications for Use	Spinal needles are indicated for the **injection of local anesthetics** into a patient **to provide regional anesthesia**.	The Portex® Lancet Point and Pencil Point Spinal Needles with NRFit™ connectors are indicated for the injection of local anesthetics or narcotics to provide regional anesthesia or withdrawal of cerebrospinal fluid when used with compatible components. The intended target population is pediatrics and adults.	Similar. Both are indicated for the injection of local anesthetics, and to provide regional anesthesia.
Hospital Location Use	ICU/OR	ICU/OR	Same

- Withdrawal of cerebrospinal fluid (CSF) using spinal needles is also indicated for similar devices. Please refer to K112515.

Characteristic	Predicate Device K983858	Subject Device	Discussion
Connector	ISO 594 Luer	ISO 80369-6 NRFit™	ISO 80369-6 NRFit™ connector intended to reduce risk of misconnections. Both met the requirements of the respective standards recognized by FDA.
Tip Design	Pencil, Lancet	Pencil, Lancet	Same
Packaging	Tyvek pouch	Tyvek pouch	Same
Sterility	Sterile, EO	Sterile, EO	Same
Use	Single Use Disposable	Single Use Disposable	Same
Needle Gauge	Pencil: 22-25 Lancet: 18-25	Pencil: 22-27 Lancet: 22-27	Similar. Needle gauge of subject device includes a 27 gauge needle in addition to the range of the predicate. The use of a 27 gauge needle is physician preference. The use of a 27 gauge needle is physician preference. The use of a 27 gauge needle is physician preference. 18-27G Spinal Needles are also being offered by other manufacturers such as Unisis Corporation (K141126).
Needle Length (mm)	Pencil: 50.8-152.4 Lancet: 50.8-152.4	Pencil: 90-152 Lancet: 38-152	Similar. Subject device length is similar to predicate's length. The shorter spinal needle is to satisfy physician preference when using accepted clinical methods.
Cannula Material	Stainless steel	Stainless steel	Same
Needle Hub Material	Polycarbonate	Polycarbonate	Same
Sheath Material	Polyethylene	Polyethylene	Same

- The differences of the NRFit and Luer connector is a matter of connection. The introduction of the spinal needles to the intrathecal space is not altered and therefore does not raise different questions of safety and effectiveness. Collection of cerebral spinal fluid through the needle with either connector does not change and therefore does not raise different questions of safety and effectiveness. The injection of local anesthetics and narcotics into the intrathecal space require a specific NRFit syringe for use in the neuroaxial procedure. This difference reduces the risk of misconnection. NRFit needles and syringes are designed for neuroaxial procedures and using this system inhibits mis-injection of medications not designed for neuroaxial procedures.

7. SUMMARY OF NON-CLINICAL TESTING

The PORTEX® Spinal Needles with NRFit™ connectors were evaluated via non-clinical performance testing to demonstrate the devices are substantially equivalent to the predicate devices. All testing met pre-established specifications, and successfully demonstrated that the PORTEX® Spinal Needles with NRFit™ connectors performed as intended. A summary of the evaluation is provided in **Table 2**.

Table 2: Summary of Non-Clinical Testing

Category	Evaluation	Test Criteria
Functional Performance	Resistance to overriding	ISO 80369-6, Small bore connectors for liquids and gases in healthcare applications - part 6: connectors for neuraxial applications
	Resistance to separation from axial load	ISO 80369-6, Small bore connectors for liquids and gases in healthcare applications - part 6: connectors for neuraxial applications
	Resistance to separation from unscrewing	ISO 80369-6, Small bore connectors for liquids and gases in healthcare applications - part 6: connectors for neuraxial applications
	Resistance to overriding	ISO 80369-6, Small bore connectors for liquids and gases in healthcare applications - part 6: connectors for neuraxial applications
	Leakage by Pressure Decay	ISO 80369-6, Small bore connectors for liquids and gases in healthcare applications - part 6: connectors for neuraxial applications
	Subatmospheric Pressure Stress Cracking	ISO 80369-6, Small bore connectors for liquids and gases in healthcare applications - part 6: connectors for neuraxial applications
	Verifying Non-interconnectable characteristics physical force	ISO 80369-6, Small bore connectors for liquids and gases in healthcare applications - part 6: connectors for neuraxial applications
Packaging	Package integrity, sterile barrier	ISO 11607, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
Sterilization	Sterility	ISO 11135, Sterilization of health care products - Ethylene Oxide - Requirements for development, validation and routine control of a sterilization process for medical devices.
	Residuals	ISO 10993-7, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
Biocompatibility	Intracutaneous Reactivity	ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
	Systemic Toxicity	ISO 10993-11, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
	Sensitization	ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
	Cytotoxicity	ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
	Genotoxicity, carcinogenicity and reproductive toxicity	ISO 10993-3, Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity
	Leachable substances	ISO 10993-17, Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances.

Category	Evaluation	Test Criteria
	Chemical characterization of materials	ISO 10993-18, Biological evaluation of medical devices - Part 18: Chemical characterization of materials
	Bacterial endotoxins	ANSI/AAMI ST72, Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing
	Particulate matter	USP 788, Particulate Matter in Injections

8. SUBSTANTIAL EQUIVALENCE CONCLUSION

The evaluation of the Smiths Medical PORTEX® Spinal Lancet Point Needles with NRFit™ connector and the PORTEX® Spinal Pencil Point Needles with NRFit™ connector device classification, indications for use, and technological characteristics demonstrate substantial equivalence to the predicate devices. Device testing met pre-defined acceptance criteria and demonstrated substantial equivalence to the predicate device.