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: K172823
Trade/Device Name: Portex® NRFit™ Epidural Needles
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: May 11, 2018
Received: May 14, 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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number *(if known)*
K172823

Device Name

PORTEX® NRFit™ Epidural Needles

Indications for Use *(Describe)*

The PORTEX® Tuohy and Hustead Needles with NRFit™ connectors are intended to facilitate the placement of an epidural catheter and for the injection or infusion of regional anesthetics or narcotics.

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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1. ADMINISTRATIVE INFORMATION

510(k)	K172823
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 needles
Primary Product Codes	BSP
Classification	Class II
Trade Name	PORTEX® NRFit™ Epidural Needles

2. REASON FOR SUBMISSION

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

3. DEVICE INFORMATION

	Predicate Device	Subject Device
Trade Name	PORTEX® Tuohy Epidural Needles	PORTEX® NRFit™ Epidural Needles
Regulation No.	21CFR868.5150	21CFR868.5150
Regulation Name	Anesthesia conduction needle	Anesthesia conduction needle
Regulatory Class	II	II
Product Code	BSP	BSP
510(k)	K090261	K172823

4. DEVICE DESCRIPTION

The PORTEX® Tuohy and Hustead Needles with NRFit™ connectors are intended to facilitate the placement of an epidural catheter for the injection or infusion of regional anesthetics or narcotics.
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™ Epidural 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® NRFit™ Epidural Needles. A description of the configuration is provided in the table below.

Device Type	Description
PORTEX® NRFit™ Epidural Needles:	The sterile, single use Tuohy and Hustead needles with NRFit™ connector are for insertion into the epidural space for either single shot doses of anesthetic or narcotics or as an introducer for epidural catheters or spinal needles. The Tuohy needles are marked at 10 mm graduations to enable the depth of needle insertion to be determined. The Tuohy needles are supplied with a removable wing which allow the needle to be used as a winged or non-winged needle. The stylet hub is color- coded for ease of identification. The intended target population is pediatrics and adults.

5. INDICATIONS FOR USE

Device Category	Indications for Use
PORTEX® NRFit™ Epidural Needles:	The PORTEX ® Tuohy and Hustead Needles with NRFit™ connectors are intended to facilitate the placement of an epidural catheter for the injection or infusion of regional anesthetics or narcotics.

6. SUBSTANTIAL EQUIVALENCE DISCUSSION

The Smiths Medical PORTEX® NRFit™ Epidural Needles have the same technological characteristics as the predicate devices with the exception of the NRFit™ Connectors.
The Smiths Medical PORTEX® NRFit™ Epidural Needles and predicate devices are both designed for the injection or infusion of regional anesthetics or narcotics. They are both made of the same materials, have the same chemical composition, and have the same design features excluding the NRFit ™ connector design. A comparative analysis is in **Table 1**.

Table 1: PORTEX® NRFit™ Epidural Needles

Characteristic	Predicate Device K090261	Subject Device	Discussion
Company	Smiths Medical	Smiths Medical	N/A
FDA Product Code & CFR	BSP 21 CFR 868.5150	BSP 21 CFR 868.5150	Same
Regulation Name	Anesthesia conduction needle	Anesthesia conduction needle	Same
Regulatory Class	II	II	Same
Trade Name	PORTEX® Tuohy Epidural Needles	PORTEX® NRFit™ Epidural Needles	N/A
Common Name	Epidural Anesthesia Needles	Epidural Anesthesia Needles	Same
Indications for Use	An Epidural Needle is indicated for the injection of anesthetic agents into the epidural space or to facilitate the placement of an epidural catheter.	The PORTEX® Tuohy and Hustead Needles with NRFit™ connectors are intended to facilitate the placement of an epidural catheter for the injection or infusion of regional anesthetics or narcotics.	Similar. Both are used for the injection of anesthetics and facilitate the placement of an epidural catheter.
Hospital Location Use	ICU/OR	Same	N/A

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 and these standards are recognized by FDA.
Tip Design	Tuohy	Tuohy, Hustead	Same, with addition of Hustead
Packaging	Tyvek pouch	Same	N/A
Sterility	Sterile, EO	Same	N/A
Use	Single Use Disposable	Same	N/A
Needle (Gauge)	17, 18	Tuohy: 16-20 Hustead: 18	Similar. These ranges have been expanded to meet clinical requirements for the patient population. The 16-20 Guage needles are also being offered by other manufacturers such as Unisis Corporation (K141126).
Needle Length (mm)	Tuohy: 90	Tuohy: 50-110 Hustead: 90	Similar. These ranges have been expanded to meet clinical requirements for the patient population.
Cannula Material	Stainless steel	Same	N/A
Needle Hub Material	Polycarbonate	Same	N/A
Sheath Material	Polyethylene	Same	N/A
Removable Wing	Polyethylene	Same	N/A

7. SUMMARY OF NON-CLINICAL TESTING

The PORTEX® NRFit™ Epidural Needles were evaluated via non-clinical performance testing to demonstrate the devices are as safe, as effective, and the subject device is substantially equivalent to the predicate device. All testing met pre-established specifications, and successfully demonstrated that the PORTEX® NRFit™ Epidural Needles 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
	Stiffness Characteristics	ISO 9626-2016, 5.8- Stiffness (Annex B)
	Bending Force	ISO 9626:2016, 5.8- Stiffness (Annex B)
	Penetration Force	PWI-10005073-Test Method for Needle Penetration Force for Epidural, Spinal and Peripheral Nerve Block
	Deflection Force	ISO 9626:2016, 5.8-Stiffness (Annex B)
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

	Hemocompatibility	ISO 10993-4, Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
	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.
	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® NRFit™ Epidural Needles device classification, indications for use, and technological characteristics demonstrate substantial equivalence to the predicate devices. Device testing met pre-defined acceptance criteria and did not raise different question of safety or effectiveness.