June 1, 2018

Smiths Medical ASD, Inc.
Sunita Teekasingh
Senior Principal Regulatory Affairs Specialist
6000 Nathan Lane North
Minneapolis, Minnesota 55442

Re: K172410
Trade/Device Name: PORTEX® LOR Syringe with NRFit™ Connector
PORTEX® EpiFuse Catheter with NRFit™ Connector
PORTEX® Epidural Flat Filter with NRFit™ Connector
PORTEX® Filter Needle with NRFit™ Connector
PORTEX® Filter Straw with NRFit™ Connector
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: Class II
Product Code: CAZ
Dated: May 3, 2018
Received: May 4, 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,

Michael J. Ryan -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

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

Indications for Use

510(k) Number *(if known)*
K172410

Device Name

PORTEX® LOR Syringe with NRFit™ Connector
PORTEX® EpiFuse Catheter with NRFit™ Connector
PORTEX® Epidural Flat Filter with NRFit™ Connector
PORTEX® Filter Needle with NRFit™ Connector and PORTEX® Filter Straw with NRFit™ Connector

Indications for Use *(Describe)*

PORTEX® products and components with the NRFit™ Connector are intended for the injection or infusion of regional anesthetics or narcotics.

The PORTEX® LOR Syringe with NRFit™ Connector is intended for use with the NRFit™ compatible components to verify needle tip placement in the epidural space by the Loss of Resistance technique using air or saline. The NRFit™ Connector is designed to be used with regional anesthesia systems only.

The PORTEX® EpiFuse Catheter with NRFit™ Connector is intended for use with the catheter and compatible components for the injection or infusion of regional anesthetics or narcotics. The key is a tool for re-opening the catheter connector.

The PORTEX® Epidural Flat Filter with NRFit™ Connector is designed for use when administering injections and/or infusions of regional anesthetics or narcotics to a patient via compatible system components. The NRFit™ Connector is designed to be used with regional anesthesia systems only.

The PORTEX® Filter Needle with NRFit™ Connector and PORTEX® Filter Straw with NRFit™ Connector are intended to draw up medication when using the PORTEX® LOR Syringe.

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."

1. ADMINISTRATIVE INFORMATION

510(k)	K172410
Applicant's Name and Address	Smiths Medical ASD, Inc. 6000 Nathan Lane North Minneapolis, MN 55442 USA
Contact Person	Sunita Teekasingh RN, BSN, CCRN Senior Principal Regulatory Affairs Specialist Vascular Access and Infusion Regulatory Affairs Interim Manger Smiths Medical ASD, Inc. 6000 Nathan Lane North Minneapolis, MN 55442 sunny.teekasingh@smiths-medical.com Phone: (763) 383-3336
Date	May 31, 2018
Regulation No.	21 CFR 880.5140
Regulation Name	Anesthesia conduction kit, and Anesthesia conduction needle
Primary Product Codes	CAZ
Trade Name	PORTEX® LOR Syringe with NRFit™ Connector PORTEX® EpiFuse Catheter with NRFit™ Connector PORTEX® Epidural Flat Filter with NRFit™ Connector PORTEX® Filter Needle with NRFit™ Connector PORTEX® Filter Straw with NRFit™ Connector

2. REASON FOR SUBMISSION

The purpose of this submission is to make a modification to the currently marketed Smiths Medical PORTEX® LOR Syringe with NRFit™ Connector, PORTEX® EpiFuse Catheter with NRFit™ Connector, PORTEX® Epidural Flat Filter with NRFit™ Connector, PORTEX® Filter Needle with NRFit™ Connector, PORTEX® Filter Straw with NRFit™ Connector are being updated to include an ISO 80369-6 compliant connector for neuraxial applications.

3. DEVICE INFORMATION

	Predicate Device	**Subject Device**
Trade Name	CorrectInject Syringe	PORTEX® LOR Syringe with NRFit™ connector
Regulation No.	21CFR868.5140	21CFR868.5140
Regulation Name	Anesthesia conduction kit	Anesthesia conduction kit
Regulatory Class	II	II
Product Code	CAZ	CAZ
510(k)	K110053	K172410
	Predicate Device	**Subject Device**
Trade Name	CorrectInject Catheter Connector	PORTEX® EpiFuse Catheter with NRFit™ Connector
Regulation No.	21CFR868.5140	21CFR868.5140
Regulation Name	Anesthesia conduction kit	Anesthesia conduction kit

Regulatory Class	II	II
Product Code	CAZ	CAZ
510(k)	K110053	K172410
	Predicate Device	**Subject Device**
Trade Name	CorrectInject Filter	PORTEX® Filter Needle with NRFit™ Connector and PORTEX® Filter Straw with NRFit™ Connector
Regulation No.	21CFR868.5140	21CFR868.5140
Regulation Name	Anesthesia conduction kit	Anesthesia conduction kit
Regulatory Class	II	II
Product Code	CAZ	CAZ
510(k)	K110053	K172410
	Predicate Device	**Subject Device**
Trade Name	CorrectInject Filter Needle, CorrectInject Filter Straw	PORTEX® NRFit™ Filter Needle,
Regulation No.	21CFR868.5140	21CFR868.5140
Regulation Name	Anesthesia conduction kit	Anesthesia conduction kit
Regulatory Class	II	II
Product Code	CAZ	CAZ
510(k)	K110053	K172410

4. DEVICE DESCRIPTION

The PORTEX® Regional Anesthesia Portfolio with NRFit™, consisting of five (5) categories of product including PORTEX® LOR Syringe with NRFit™ Connector, PORTEX® EpiFuse Catheter with NRFit™ Connector, PORTEX® Epidural Flat Filter with NRFit™ Connector and the PORTEX® Filter Straw with NRFit™ Connector.

PORTEX® products and components with NRFit™ connector are intended for the injection or infusion of regional anesthetics or narcotics.

The NRFit ™ connector conform to ISO 80369-6, Small bore connector for liquids and gases in healthcare applications -- Part 6: Connectors for neuraxial applications. The connectors are not compatible with standard luer connectors which are 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® Regional Anesthesia Portfolio with NRFit™ connector 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® Regional Anesthesia Portfolio devices with NRFit™ Connector. A description of each configuration is provided in the table below.

Device Type	Description
PORTEX® LOR Syringe with NRFit™ Connector	The Loss of Resistance (LOR) syringes are a range of sterile, single use syringes used as an aid in locating the epidural space using the Loss of Resistance technique. PORTEX® LOR syringes are available in glass or plastic, and 5, 7, and 10 mL sizes.
PORTEX® EpiFuse Catheter with NRFit™ Connector:	The Catheter Connector is designed to provide a secure interface between the catheter and the delivery system. The key is a tool for re-opening the catheter connector. The Catheter Connector includes a Thread Assist Guide which provides support for the catheter threading.
PORTEX® Epidural Flat Filter with NRFit™ Connector:	The Epidural Flat Filter is a microporous filter used to minimize particulate (foreign material) contamination of fluids and drugs.
PORTEX® PORTEX® Filter Needle with NRFit™ Connector and PORTEX® Filter Straw with NRFit™ Connector:	The PORTEX® NRFit™ Filter Needle and Filter Straw is used to draw up medication when using an NRFit™ Syringe.

5. INDICATIONS FOR USE

PORTEX® products and components with the NRFit™ Connector are intended for the injection or infusion of regional anesthetics or narcotics.

Device Category	Indications for Use
PORTEX® LOR Syringe with NRFit™ Connector:	The PORTEX® LOR Syringe with NRFit™ Connector is intended for use with NRFit™ compatible components to verify needle tip placement in the epidural space by the Loss of Resistance technique using air or saline. The NRFit™ connector is designed to be used with regional anesthesia systems only.
PORTEX® EpiFuse Catheter with NRFit™ Connector	The PORTEX® EpiFuse Catheter with NRFit™ Connector is intended for use with the catheter and compatible components for the injection or infusion of regional anesthetics or narcotics. The key is a tool for re-opening the catheter connector.
PORTEX® Epidural Flat Filter with NRFit™ Connector:	PORTEX® Epidural Flat Filter with NRFit™ Connector is designed for use when administering injections and/or infusions of regional anesthetics or narcotics to a patient via compatible system components. The NRFit™ Connector is designed to be used with regional anesthesia systems only.
PORTEX® Filter Needle with NRFit™ Connector and PORTEX® Filter Straw with NRFit™ Connector	The PORTEX® Filter Needle with NRFit™ Connector and PORTEX® Filter Straw with NRFit™ Connector are intended to draw up medication when using the PORTEX® LOR Syringe.

6. SUBSTANTIAL EQUIVALENCE DISCUSSION

The Smiths Medical PORTEX® LOR Syringe with NRFit™ Connector, PORTEX® EpiFuse Catheter with NRFit™ Connector, PORTEX® Epidural Flat Filter with NRFit™ Connector, PORTEX® Filter Needle with NRFit™ Connector and PORTEX® Filter Straw with NRFit™ Connector have the same technological characteristics as the predicate devices with the exception of the NRFit TM Connectors.

The main difference is the NRFit™ connectors, which 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 are intended to reduce the risk of misconnection that may result in the infusion of medications not intended for

neuraxial or regional anesthetic use.

The Smiths Medical PORTEX® Regional Anesthesia Portfolio with NRFit™ and predicate devices are both designed for the injection or infusion of regional anesthetics or narcotics.

Subject and predicate are made of similar materials, similar size ranges, chemical composition, and have the same design features excluding the NRFit ™ connector design.

Potential risks introduced by the 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 the following Tables;

Table 1: PORTEX® LOR Syringes with NRFit™ Connector

Characteristic	**Predicate Device K110053**	**Subject Device**	**Discussion**
Company	Smiths Medical	Smiths Medical	N/A
FDA Product Code & CFR	CAZ 21 CFR 868.5140	CAZ 21 CFR 868.5140	Same
Regulation Name	Anesthesia conduction kit	Anesthesia conduction kit	Same
Regulatory Class	II	II	Same
Trade Name	CorrectInject Syringe	PORTEX® LOR Syringe with NRFit™ Connector	N/A
Common Name	Syringe	Loss of Resistance Syringe	Similar. Subject is a more specific application type of syringe.
Indications for Use	The CorrectInject **Syringe** is intended for use with CorrectInject compatible components for the injection of medications.	The PORTEX® L.O.R. Syringe with NRFit™ Connector is intended for use with NRFit™ compatible components to verify needle tip placement in the epidural space by the Loss of Resistance technique using air or saline. NRFit™ connectors are designed to be used with regional anesthesia systems only.	Similar. Both are **syringes** that are used with compatible components for injection. Predicate is intended for CorrectInject compatible components for the injection of medications. Subject is intended for use with NRFit™ compatible components to verify needle tip placement in the epidural space by the Loss of Resistance technique, and designed to be used with regional anesthesia systems only. This difference does not raise different questions of safety and effectiveness.
Hospital Location Use	ICU/OR	ICU/OR	Same

Characteristic	Predicate Device K110053	Subject Device	Discussion
Connector	Neuraxial safety system	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	Lock and slip tip	Lock and slip tip	Same
Packaging	Tyvek pouch	Tyvek pouch	Same
Sterility	Sterile, EO	Sterile, EO	Same
Use	Single Use Disposable	Single Use Disposable	Same
mL	3, 5, 10, 20	5, 7 and 10	Subject capacity is different than predicate's mL range due to the specific application of the LOR syringe.
Material	Polypropylene and poly - isoprene	Polypropylene, Isobutylene/isoprene rubber tip	Similar. Subject uses isoprene and predicate uses poly isoprene. Plastic syringe contains Polypropylene in both Subject and predicate. Glass syringe is different. Subject made of glass, predicate made of polypropylene.

Table 2: Syringe – Characteristic Comparison

Characteristics	Predicate Device	Subject	SE Rationale	Risk Impact
Syringe Volume capacity (ml)	Volume/size of in subject=5, 7, 10 ml ml in predicate = 3, 5, 10, 20 ml	Subject has a 7 ml size, which is within range of the 5 and 10ml predicate device sizes.	Subject capacity is different than predicate's mL range due to the specific application of the LOR syringe.	No risk: The LOR is not used clinically for a precise injection of fluids. The physician will add an approximate amount per their preference to perform the LOR technique with. As such, the volume markings are for reference.
Material in glass syringe	Glass	Subject uses glass with a metal - nickel and chrome plated brass. ISO 80369-6 tip	The body of the syringes is the same glass material. The NRFit™ LOR syringe has a metal tip that meets ISO 80369-6 dimensions. Biocompatibility testing was performed on the NRFit™ Glass LOR with passing results.	No risk impact - Materials were verified through biocompatibility testing.
Connector	CorrectInject	NRFit™ connector in subject	The difference is the subject uses an ISO 80369-6 NRFit™ connector. This is an industry standard design as opposed to the CorrectInject proprietary standard.	Risk reduction to avoid misconnections.
Indications For Use	The predicate is intended for CorrectInject compatible components for the injection of medications.	Subject and predicate are both syringes that are used with compatible components for injection. Subject is intended for NRFit™ compatible components to verify needle tip	The subject IFU contains additional information to clarify clinical use.	No risk. Additional information to clarify use.

Characteristics	Predicate Device	Subject	SE Rationale	Risk Impact
		placement in the epidural space by the Loss of Resistance technique using air or saline. NRFit™ connectors are designed to be used with regional anesthesia systems only.		

Table 3: PORTEX® EpiFuse Catheter with NRFit™ Connector

Characteristic	Predicate Device K110053	Subject Device	Discussion
Company	Smiths Medical	Smiths Medical	N/A
FDA Product Code & CFR	CAZ 21 CFR 868.5140	CAZ 21 CFR 868.5140	Same
Regulation Name	Anesthesia conduction kit	Anesthesia conduction kit	Same
Regulatory Class	II	II	Same
Trade Name	CorrectInject Catheter Connector	PORTEX® EpiFuse Catheter with NRFit™ Connector	N/A
Common Name	Catheter Connector	Catheter Connector	Same
Indications for Use	The CorrectInject Catheter Connector is intended for use with an epidural anesthesia catheter and CorrectInject compatible components for the injection of local or regional anesthetics, narcotics or other medications indicated for injection into the epidural space.	The PORTEX® EpiFuse Catheter with NRFit ™ Connector is intended for use with a catheter and compatible components for the injection or infusion of regional anesthetics or narcotics. The key is a tool for re-opening the catheter connector.	Similar. Both used with a catheter. Both are indicated for regional anesthetics or narcotics, and both to be used with compatible components. This difference does not raise different questions of safety and effectiveness.
Hospital Location Use	ICU/OR	ICU/OR	Same
Connector	CorrectInject 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

Characteristic	Predicate Device K110053	Subject Device	Discussion
			these standards are recognized by FDA.
Packaging	Tyvek pouch	Tyvek pouch	Same
Sterility	Sterile, EO	Sterile, EO	Same
Use	Single Use Disposable	Single Use Disposable	Same
Compatible Needle Length (mm)	16-19	16-19	Same
Catheter Connector - Material	Polypropylene body with a thermoplastic elastomer tube	Polypropylene body with a thermoplastic elastomer tube	Same

Table 4: Catheter Connector – Characteristic Comparison

Characteristic	Predicate	Subject Device	SE Rationale	Risk Impact
Catheter connector :	The predicate uses a luer tip syringe to re-open the catheter connector	Subject uses a key as a tool for re-opening the catheter connector	Both devices require the use of a secondary tool to open the connector The NRFit™ connector requires a specially designed tool as the slip NRFit™ connector has a shroud that surrounds the cone	Risk reduction as Luer syringes cannot open the NRFit™ catheter connector.
Connector	CorrectInject Luer	NRFit™ connector in subject	Subject uses an ISO 80369-6 NRFit™ connector, which is designed to reduce risk of misconnections.	Risk reduction to avoid misconnections.

Table 5: PORTEX® Epidural Flat Filter with NRFit™ Connector

Characteristic	Predicate Device K110053	Subject Device	Discussion
Company	Smiths Medical	Smiths Medical	N/A
FDA Product Code & CFR	CAZ 21 CFR 868.5140	CAZ 21 CFR 868.5140	Same
Regulation Name	Anesthesia conduction kit	Anesthesia conduction kit	Same
Regulatory Class	II	II	Same
Trade Name	CorrectInject Filter	PORTEX® Epidural Flat Filter with NRFit™ Connector	N/A
Common Name	Flat Filter	Flat Filter	Same

Characteristic	Predicate Device K110053	Subject Device	Discussion
Indications for Use	The CorrectInject anesthesia conduction filter is a microporous filter used while administering to a patient **injections** of local **anesthetics** to minimize particulate (foreign material) contamination of the injected fluid when used with CorrectInject compatible components.	The PORTEX® Epidural Flat Filter with NRFit™ connectors is designed for use when administering **injections** and/or infusions of regional **anesthetics** or narcotics to a patient via compatible system components. NRFit™ connectors are designed to be used with regional anesthesia systems only.	Similar. Both are indicated for filter application for injection of anesthetics. This difference does not raise different questions of safety and effectiveness.
Hospital Location Use	ICU/OR	ICU/OR	Same
Connector	CorrectInject 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.
Filter Pore Size (micron)	0.02	0.02	Same
Packaging	Tyvek pouch	Tyvek pouch	Same
Sterility	Sterile, EO	Sterile, EO	Same
Use	Single Use Disposable	Single Use Disposable	Same
Material	Polyether sulfone (PES) filter enclosed in a modified acrylic housing with a polypropylene rotating collar. The collar is colored yellow using a Clariant colorant.	Polyether sulfone (PES) filter enclosed in a modified acrylic housing cover, with a polypropylene rotating hub. The hub is colored yellow using a Clariant colorant.	Same

Table 6: Flat Filter – Characteristic Comparison

Characteristic	Predicate	Subject Device	SE Rationale	Risk Impact
Connector	Luer connector	NRFit™ connector	Different connector type	Risk reduction to avoid misconnections.

Table 7: PORTEX® Filter Needle with NRFit™ Connector and Filter Straw with NRFit™ Connector

Characteristic	Predicate Device K110053	Subject Device	Discussion
Company	Smiths Medical	Smiths Medical	N/A
FDA Product Code & CFR	CAZ 21 CFR 868.5140	CAZ 21 CFR 868.5140	Same

Characteristic	Predicate Device K110053	Subject Device	Discussion
Regulation Name	Anesthesia conduction kit	Anesthesia conduction kit	Same
Regulatory Class	II	II	Same
Trade Name	CorrectInject Filter Needle Filter Straw	PORTEX® NRFit™ Filter Needle with NRFit™ Connector and PORTEX® Filter Straw with NRFit™ Connector	N/A
Common Name	Anesthesia Conduction Kit	Anesthesia Conduction Kit	Same
Indications for Use – Filter Straw	The CorrectInject filter straw is intended to adapt a Luer **draw-up device** to the CorrectInject **syringe**.	The PORTEX® NRFit™ Filter Needle and Filter Straw is intended to draw up medication when using the PORTEX® Regional Anaesthesia Portfolio with NRFit™ **Syringe**.	Similar. Both connect to a syringe, and both draw up medication. This difference does not raise different questions of safety and effectiveness.
Indications for Use – Filter Needle	The CorrectInject filter needle is intended to **draw up** medication when using the CorrectInject **Syringe**.	The PORTEX® NRFit™ Filter Needle and Filter Straw is intended to draw up medication when using the PORTEX® Regional Anaesthesia Portfolio with NRFit™ Syringe.	Similar. Both connect to a syringe, and both draw up medication. This difference does not raise different questions of safety and effectiveness.
Hospital Location Use	ICU/OR	ICU/OR	Same
Connector	CorrectInject 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.
Filter Pore Size (micron)	5	5	Same
Packaging	Tyvek pouch	Tyvek pouch	Same
Sterility	Sterile, EO	Sterile, EO	Same
Use	Single Use Disposable	Single Use Disposable	Same
Filter Needle Material	Stainless steel needle with a polycarbonate hub and a polybutylene terephthalate adaptor.	Stainless steel needle with an ABS hub.	Similar. Both use stainless steel needle. Difference is hub materials with predicate made of polycarbonate and subject made of ABS.
Filter Straw Material	Polycarbonate and an acrylic copolymer attached to a polybutylene terephthalate (PBT) adaptor.	DEHP-free PVC straw tubing with an ABS hub.	Similar. Predicate hub is made of acrylic copolymer attached to a BPT adaptor and subject made from a DEHP-free PVC with ABS hub.

Table 8: Filter Needle – Characteristic Comparison

Characteristic	Predicate	Subject Device	SE Rationale	Risk Impact
Material	Polycarbonate	ABS	Needle and filter materials are similar.	Risk mitigated - The materials incorporated in the NRFit™ Filter Needle are suitable for the devices' intended use and do not pose a biological risk to clinical subjects.
Connector	Luer connector	NRFit™ connector	Different connector type	Risk reduction to avoid misconnections.

Table 9: Filter Straw – Characteristic Comparison

Characteristic	Predicate	Subject Device	SE Rationale	Risk Impact
Material	PVC straw and a polycarbonate filter housing with a PBT CorrectInject connector.	PVC straw with an ABS NRFit™ hub/filter housing	Different material type	No risk impact – The materials incorporated in the NRFit™ Filter Straw are suitable for the devices' intended use and do not pose a biological risk to clinical subjects.
Connector	Luer connector	NRFit™ connector	Different connector type	Risk reduction to avoid misconnections.

7. SUMMARY OF NON-CLINICAL TESTING

The PORTEX® Regional Anesthesia Portfolio with NRFit™ Connector were evaluated via non-clinical performance testing to demonstrate the devices are as safe, as effective, and perform as well as or better than the predicate devices. All testing met pre-established specifications, and successfully demonstrated that the PORTEX® Regional Anesthesia Portfolio with NRFit™ connectors performed as intended. A summary of the evaluation is provided below in **Table 10**.

Table 10: 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® Regional Anesthesia Portfolio with NRFit™ connector device classification, indications for use, and technological characteristics demonstrate substantial equivalence to the predicate devices. The differences in technological characteristics do not raise different questions, and testing meets the acceptance criteria and demonstrates Substantial Equivalence.