November 26, 2021

Smiths Medical ASD, Inc.
Nancy Deangelo
Manager, Regulatory Affairs
6000 Nathan Lane North
Minneapolis, Minnesota 55442

Re: K210833
Trade/Device Name: Portex BLUxl Extra Length Tracheostomy Tube, BLUxl Suctionaid Extra Length Tracheostomy Tube, BLUxl Extra Length Tracheostomy Inner Cannula
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube And Tube Cuff
Regulatory Class: Class II
Product Code: JOH
Dated: July 30, 2021
Received: October 25, 2021

Dear Nancy Deangelo:

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,

Todd Courtney
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K210833

Device Name
Portex® BLUxl™ Extra Length Tracheostomy Inner Cannula

Indications for Use *(Describe)*
The Portex® BLUxl™ Extra Length Tracheostomy Inner Cannula is intended to be used with the Portex® BLUxl™ Extra Length Tracheostomy Tube indicated for airway maintenance of tracheostomy patients.

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."

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)*
K210833

Device Name
Portex® BLUxl™ Extra Length Tracheostomy Tube

Indications for Use *(Describe)*
Portex® BLUxl™ Extra Length Tracheostomy Tube is indicated for airway maintenance of tracheostomised patients.

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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5 510(k) Summary

Sponsor:	Smiths Medical ASD, Inc. 6000 Nathan Lane North Minneapolis, MN 55442 763.383.3000
Date Prepared:	March 17, 2021 (revised November 22, 2021)
Proprietary Name:	Portex® BLUxl™ Extra Length Tracheostomy Tube, Portex® BLUxl™ Suctionaid® Extra Length Tracheostomy Tube, and Portex® BLUxl™ Extra Length Tracheostomy Inner Cannula
Classification Name:	JOH- Tube, Tracheostomy Tube and Tube Cuff
Classification:	Class: II Regulation Number: 21 CFR 868.5800 Product Code: JOH - Tube, Tracheostomy Tube and Tube Cuff
Predicate device:	Smiths Medical BLUselect® Tracheostomy Tube, BLUselect® Suctionaid® Tracheostomy Tube and BLUselect® Tracheostomy Tube Inner Cannula (K173384, cleared on April 10, 2018).
Device Description:	Portex® BLUxl™ Extra Length Tracheostomy Tubes and BLUxl™ Suctionaid® Extra Length Tracheostomy Tubes are designed to aid the adult population who require an artificial airway due to trauma or medical condition. Patients who benefit from this procedure are those who: require prolonged intubation for mechanical ventilator support; cannot manage their airway secretions; or have an upper airway obstruction. Portex® BLUxl™ Extra Length Tracheostomy Inner Cannula is intended to be used with the Portex® BLUxl™ Extra Length Tracheostomy Tubes and Portex® BLUxl™ Suctionaid® Extra Length Tracheostomy Tubes. The inner cannulas are single use only. A detailed description of the Portex® BLUxl™ Extra Length Tracheostomy Tube, Portex® BLUxl™ Suctionaid® Extra Length Tracheostomy Tube, and Portex® BLUxl™ Extra Length Tracheostomy Inner Cannula is provided in **Section 10** Device Description.
Intended Use:	Portex® BLUxl™ Extra Length Tracheostomy Tube is for the adult patient category that require an artificial airway due to trauma or medical condition. Maximum recommended period of use is 29 days. 200/710, 720 and 730/xxx are extra proximal length (y measurement) tracheostomy tubes and are indicated for use in patients with excessive skin surface to anterior tracheal wall distance as frequently seen in obesity. 200/715, 725 and 735/xxx are extra distal length (x measurement) tracheostomy tubes and are indicated for use in patients with normal skin surface to anterior tracheal wall distance and require the distal length of the tracheostomy tube to extend more caudally within the trachea.

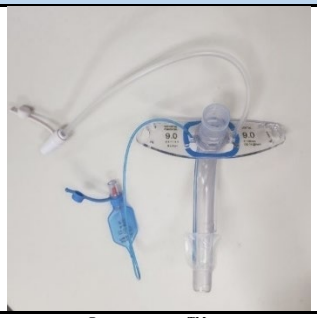
	The Portex® BLUxl™ Extra Length Tracheostomy Inner Cannula is intended to be used with the Portex® BLUxl™ Extra Length Tracheostomy Tube for patients that require an artificial airway due to trauma or medical condition. Maximum recommended period of use is 29 days.
Indications for use:	Portex® BLUxl™ Extra Length Tracheostomy Tube is indicated for airway maintenance of tracheostomised patients. The Portex® BLUxl™ Extra Length Tracheostomy Inner Cannula is intended to be used with the Portex® BLUxl™ Extra Length Tracheostomy Tube indicated for airway maintenance of tracheostomy patients.
Non-clinical Performance Data:	Non-clinical testing of the components comprised in each configuration of the subject devices, Portex® BLUxl™ Extra Length Tracheostomy Tube, Portex® BLUxl™ Suctionaid® Extra Length Tracheostomy Tube, and Portex® BLUxl™ Extra Length Tracheostomy Inner Cannula were assessed and tested appropriately to design controls, i.e. design verification, design validations. The test results conclude that for Portex® BLUxl™ Extra Length Tracheostomy Tube, Portex® BLUxl™ Suctionaid® Extra Length Tracheostomy Tube, and Portex® BLUxl™ Extra Length Tracheostomy Inner Cannula are to be substantially equivalent to the predicate device described herein. Testing listed below passed and were verified against their requirements: • Mechanical Testing o Testing included: Dimensional requirements (such as Tracheostomy tube outer diameter, Tube overall length, Tube inner diameter at the patient end and 15mm connector taper gauging) and mechanical requirements (such as Tube kink resistance, Tensile strength of flange, Cuff inflation/deflation, Cuff resting diameter, Cuff herniation, Cuff attachment, Cuff burst, puncture and leak resistance, Inner Cannula insertion/removal cycling, Obturator insertion and fallout and Robustness of product markings). • Artificially Aged Sample Testing o Testing included: 6-month, 2-year, 3-year and 5-year artificially aged samples tested to design requirements. Additionally, real time aging will be carried out for the same time periods. • Magnetic Resonance Imaging (MRI) o Rationale provided utilizing legacy testing data. • Cleaning Instruction Validation o Cleaning validation of BLUxl™ Extra Length Tracheostomy Inner Cannula. o Cleaning validation of external surface of the BLUxl™ Extra Length Tracheostomy Tube. • Biocompatibility o Testing evaluated: Cytotoxicity, Sensitization, Irritation, Acute System Toxicity, Pyrogenicity, Subchronic Toxicity, Genotoxicity and Implantation.

	• Sterilization
	  ○ Validations, in accordance with ISO 11135:2014, ISO 11138-1:2017, ISO 11137-1:2018, ISO 11737-2:2020, and ISO 10993-7:2008 have been completed demonstrating results which indicate the subject devices are acceptable and can be distributed sterile to meet with the minimum sterility assurance level (SAL) of 10^{-6} per ISO 11135.
	• Packaging
	  ○ Testing was performed to ASTM F2096-11 and ASTM F88-15, with passing results.

Biocompatibility	**Contact classifications:** Externally Communicating – Tissue, Surface Device – Mucosal Membrane, Surface Device – Intact Skin **Duration:** up to 29 days, prolonged
Clinical Performance Data:	Clinical testing was not necessary for the determination of substantial equivalence.
Substantial Equivalence:	Smiths Medical considers the subject devices, Portex® BLUxl™ Extra Length Tracheostomy Tube, BLUxl™ Suctionaid® Extra Length Tracheostomy Tube, and BLUxl™ Extra Length Tracheostomy Inner Cannula to be substantially equivalent to the predicate device, Smiths Medical BLUselect® Tracheostomy Tube, BLUselect® Suctionaid Tracheostomy Tube and BLUselect® Inner Cannula because there are no significant differences between the devices in intended use, mechanical and functional performance and all utilize the same functional scientific technology. The predicate 510(k) Summary is provided in **Attachment 3**. Smiths Medical has demonstrated there are no new issues of safety and effectiveness raised due to the similarities and/or differences between the subject and predicate/commercialized devices, as each are used to treat the same clinical conditions and represent a similar/basic design concept. The table below provides a substantial equivalence summary, between the BLUselect devices and the predicate devices.

Substantial Equivalence – Subject vs. Predicate Comparison

Comparator	**Subject Device:** Portex® BLUxl™ Extra Length Tracheostomy Tube, Portex® BLUxl™ Suctionaid® Extra Length Tracheostomy Tube, and Portex® BLUxl™ Extra Length Tracheostomy Inner Cannula	**Predicate Device:** BLUselect® Tracheostomy Tube and BLUselect® with Suctionaid Tracheostomy Tube and BLUselect® Inner Cannula	**Substantial Equivalence Determination**
Company	Smiths Medical ASD, Inc.	Smiths Medical ASD, Inc.	Identical
510(k)	*K210833*	K173384, cleared on April 10, 2018	N/A

Comparator	**Subject Device:** Portex® BLUxl™ Extra Length Tracheostomy Tube, Portex® BLUxl™ Suctionaid® Extra Length Tracheostomy Tube, and Portex® BLUxl™ Extra Length Tracheostomy Inner Cannula	**Predicate Device:** BLUselect® Tracheostomy Tube and BLUselect® with Suctionaid Tracheostomy Tube and BLUselect® Inner Cannula	**Substantial Equivalence Determination**
Image			N/A
Indications	Portex® BLUxl™ Extra Length Tracheostomy Tube is indicated for airway maintenance of tracheostomised patients. The Portex® BLUxl™ Extra Length Tracheostomy Inner Cannula is intended to be used with the Portex® BLUxl™ Extra Length Tracheostomy Tube indicated for airway maintenance of tracheostomy patients.	Smiths Medical Portex® BLUselect® Tracheostomy Tube is indicated for airway maintenance of tracheostomised patients. Smiths Medical Portex® BLUselect® Suctionaid® Tracheostomy Tube is indicated for airway maintenance of tracheostomised patients. Suctionaid® allows aspiration of contaminated mucous and subglottic secretions that collect and build up between the tracheostomy tube cuff and the glottis. The BLUselect® Inner Cannula is intended to be used with the Smiths Medical Portex® BLUselect® Tracheostomy Tube indicated for airway maintenance of tracheostomy patients.	Identical
Contraindications in Labeling	There are no known Contraindications associated with this product.	There are no known Contraindications associated with this product.	Identical
Product Codes	JOH	JOH	Identical
Regulation	21 CFR § 868.5800	21 CFR § 868.5800	Identical

Comparator	**Subject Device:** Portex® BLUxl™ Extra Length Tracheostomy Tube, Portex® BLUxl™ Suctionaid® Extra Length Tracheostomy Tube, and Portex® BLUxl™ Extra Length Tracheostomy Inner Cannula	**Predicate Device:** BLUselect® Tracheostomy Tube and BLUselect® with Suctionaid Tracheostomy Tube and BLUselect® Inner Cannula	**Substantial Equivalence Determination**
Intended Use	Smiths Medical Portex® BLUxl™ Extra Length Tracheostomy Tube is for the adult patient category that require an artificial airway due to trauma or medical condition. Maximum recommended period of use is 29 days. The Portex® BLUxl™ Extra Length Tracheostomy Inner Cannula is intended to be used with the Portex® BLUxl™ Extra Length Tracheostomy Tube for patients that require an artificial airway due to trauma or medical condition. Maximum recommended period of use is 29 days.	Smiths Medical Portex® BLUselect® Tracheostomy Tube is for patients that require an artificial airway due to trauma or medical condition. Maximum period of use is 29 days. (BLUselect® and BLUselect® Suctionaid®) The BLUselect® Inner Cannula is intended to be used with the Smiths Medical Portex® BLUselect® Tracheostomy Tube for patients that require an artificial airway due to trauma or medical condition. Maximum period of use is 29 days.	Identical
Single Patient Use	Yes	Yes	Identical
Patient Population	Intended for adults with above average height, weight, and anthropometrics.	Intended for adults with average height, weight, and anthropometrics.	Similar
Use Environment	Hospital environments, Home care use	Hospital environments, Home care use	Identical
Materials	**Tracheostomy Tube**: Polyvinyl Chloride (PVC)with Dioctyl Terephthalate (DEHT) plasticizer **Tracheostomy Tube Cuff:** Polyurethane (PU) **Inner Cannula:** Polytetrafluoroethylene (PTFE) and Low Density Polyethylene (LDPE) **Obturator:** High-density Polyethylene (HDPE)	**Tracheostomy Tube:** Polyvinyl Chloride (PVC)with Dioctyl Terephthalate (DEHT) plasticizer **Tracheostomy Tube Cuff:** Polyvinyl Chloride (PVC) **Inner Cannula:** Low Density Polyethylene (LDPE) or LDPE with red colorant (Fenestrated) **Obturator:** High-density polyethylene (HDPE)	Similar

Comparator	**Subject Device:** Portex® BLUxl™ Extra Length Tracheostomy Tube, Portex® BLUxl™ Suctionaid® Extra Length Tracheostomy Tube, and Portex® BLUxl™ Extra Length Tracheostomy Inner Cannula	**Predicate Device:** BLUselect® Tracheostomy Tube and BLUselect® with Suctionaid Tracheostomy Tube and BLUselect® Inner Cannula	**Substantial Equivalence Determination**
Product Configurations	Uncuffed, Cuffed, Suctionaid®	Uncuffed, Fenestrated Uncuffed, Cuffed, Fenestrated Cuffed, Suctionaid®, Fenestrated Suctionaid®	Similar
Sizes (Inner Diameter)	6.0mm, 7.0mm, 8.0mm, 9.0mm	6.0mm, 7.0mm, 7.5mm, 8.0mm, 8.5mm, 9.0mm, 9.5mm, 10.0mm	Similar
System Overview			
Standard System Components	Tracheostomy Tube, Obturator, Uncoupling Wedge, Tube Holder, Inner Cannula (x2), Patient Labels, IFU	Tracheostomy Tube, Obturator, Uncoupling Wedge, Tube Holder with Cleaning Brush, Inner Cannula (x2), Patient Labels, IFU	Similar
Suctionaid® Standard System Component	Vacuum Control Valve	Vacuum Control Valve	Identical
Flange Markings	Laser marked product information with vinyl ink pad printer color coding band	Laser marked product information with vinyl ink pad printer color coding band	Identical
Maximum Use	Recommended 29 days	Recommended 29 days	Identical
Biocompatibility	Materials compatible to ISO 10993-1:2009	Materials compatible to ISO 10993-1:2009	Identical
Sterilization	Ethylene Oxide (EO) Sterilized – SAL 10^{-6}	Ethylene Oxide (EO) Sterilized – SAL 10^{-6}	Identical
Shelf Life	Tracheostomy Tubes: 3-year shelf life Inner Cannula: 5-year shelf life	Tracheostomy Tube and Inner Cannula: 5-year shelf life	Similar

Conclusion: The subject Portex® BLUxl™ Extra Length Tracheostomy Tubes, Portex® BLUxl™ Suctionaid® Extra Length Tracheostomy Tubes, and Portex® BLUxl™ Extra Length Tracheostomy Inner Cannulas has the same indications for use and technological characteristics compared to the predicate devices. The non-clinical performance data included in this submission supports that any differences in technological characteristics from the predicate device do not raise any new questions of safety and effectiveness. It is concluded that the information provided in this submission supports substantial equivalence.