April 10, 2018

Smiths Medical ADS, Inc.
Donna Semlak
Principal Regulatory Affairs Specialist
6000 Nathan Lane North
Minneapolis, Minnesota 55442

Re: K173384
Trade/Device Name: Smiths Medical Portex® BLUselect® Tracheostomy Tube
Smiths Medical Portex® BLUselect® Suctionaid® Tracheostomy Tube
Smiths Medical Portex® BLUselect® Tracheostomy Inner Cannula
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: Class II
Product Code: BTO
Dated: March 2, 2018
Received: March 5, 2018

Dear Donna Semlak:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173384

Device Name
Smiths Medical Portex®
BLUselect® Tracheostomy Tube

Indications for Use *(Describe)*
Smiths Medical Portex® BLUselect® 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173384

Device Name
Smiths Medical Portex®
BLUselect® Suctionaid® Tracheostomy Tube

Indications for Use *(Describe)*

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.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173384

Device Name
Smiths Medical Portex®
BLUselect® Tracheostomy Inner Cannula

Indications for Use *(Describe)*

The BLUselect® Inner Cannula is intended to be used with the Smiths Medical Portex® BLUselect® 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)

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smiths medical bringing technology to life	**510(k) SUMMARY** ***BLUselect® Devices***

Date of Summary Preparation:	April 9, 2018 (revised)
Submitter:	Smiths Medical 6000 Nathan Lane Minneapolis, MN 55442 USA
Establishment Registration Number:	3012307300 (Minneapolis)
Company Contact (Primary):	Donna M. Semlak Principal Regulatory Affairs Specialist Email: donna.semlak@smiths-medical.com Office: 763-383-3076
Trade Name(s):	Tracheostomy Tube
Device Names(s):	• *Smiths Medical Portex® BLUselect® Tracheostomy Tube* • *Smiths Medical Portex® BLUselect® Suctionaid® Tracheostomy Tube* • *Smiths Medical Portex® BLUselect® Tracheostomy Inner Cannula*
Device Classification:	Class II
Regulation Number and Product Code(s):	21 CFR § 868.5800 *Tracheostomy, Tube* BTO

Purpose

The purpose of this premarket notification Traditional 510(k) is to obtain FDA clearance for adult patient population requiring an artificial airway for breathing. This submission is submitted to establish substantial equivalence and obtain 510(k) clearance for the following:

- *Smiths Medical Portex® BLUselect® Tracheostomy Tube*
- *Smiths Medical Portex® BLUselect® Suctionaid® Tracheostomy Tube*
- *Smiths Medical Portex® BLUselect® Tracheostomy Inner Cannula*

Predicate Device(s) for Smiths Medical Portex® BLUselect® Devices

Information for the predicate device is provided in the table below for the subject devices, *BLUselect®, BLUselect® Suctionaid®, and BLUselect® Inner Cannula*.

Predicate Device Name	FDA 510(k) Number and Clearance Date	Classification	Primary Code
Portex Blue Line Ultra Suctionaid Tracheostomy Tube	K030570 Sept 17, 2003 *Original Applicant: Portex Limited*	Class II	BTO 21 CFR 868.5800

Reference Devices for Smiths Medical Portex® BLUselect® Devices

Reference Device Name	FDA 510(k) Number and Clearance Date	Classification	Primary Code
Portex UniPerc Percutaneous Dilation Tracheostomy Kit	K083031 August 18, 2009 *Original Applicant: Smiths Medical*	Class II	BTO 21 CFR 868.5800
Bivona Tracheostomy Tubes *MRI Labeling*	K083641 Feb 23, 2009 *Original Applicant: Smiths Medical*	Class II	JOH 21 CFR 868.500
Blue Line Ultra Tracheostomy Tube *Includes inner cannula*	K030381 Aug 23, 2003 *Original Applicant: Portex Limited*	Class II	BTO 21 CFR 868.5800

General Device Description

Smiths Medical Portex® BLUselect®, BLUselect® Suctionaid®, and BLUselect® Inner Cannula:

The *Smiths Medical Portex® BLUselect and BLUselect Suctionaid 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. *BLUselect Inner Cannula* is intended to be used with the Smiths Medical Portex® BLUselect Tracheostomy Tubes. The subject device package consists of a tracheostomy tube, a tube holder, cleaning brush, an inner cannula, obturator, disconnection wedge, and a vacuum control valve (with Suctionaid® tubes only) and a maximum recommended period of use is 29 days; intended to be used critical care settings, acute care settings, long term care facilities, and for home use.

The tube is manufactured with a flange, inflation line, suction line and a 15mm connector. All components are manufactured from medical grade materials and have biocompatibility data for safe use when in-contact with patient tissue/bodily fluids/secretions.

Indications for Use:

Smiths Medical Product Name	Indications For Use
Smiths Medical Portex® BLUselect® Tracheostomy Tube	Smiths Medical Portex® BLUselect® Tracheostomy Tube is indicated for airway maintenance of tracheostomised patients.
Smiths Medical Portex® BLUselect® Suctionaid® Tracheostomy Tube	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.
Smiths Medical Portex® BLUselect® Tracheostomy Inner Cannula	The BLUselect® Inner Cannula is intended to be used with the Smiths Medical Portex® BLUselect® Tracheostomy Tube indicated for airway maintenance of tracheostomy patients.

Summary of Technological Characteristics:

The Smiths Medical Portex® BLUselect subject devices shares the similar technological characteristics as their 510(k) cleared predicates, Blue Line Ultra devices. These characteristics include the same intended use of 29 days for the adult patient population, same overall design, same base materials, and same range of sizes, Also, both the subject device and the predicate devices meet the ISO 5366 and ISO 5356 standards and requirements for tracheostomy tubes; including ISO 18190 for airway equipment; which concludes substantially equivalent performance characteristics.

The BLUselect subject device and the Blue Line Ultra Tracheostomy Tube predicate device are manufactured with the same type of material, Polyvinyl Chloride (PVC). The BLUselect Inner Cannula and Blue Line Ultra Inner Cannula predicate device material is a medical grade polyethylene.

The subject devices and the predicate devices are designed to aid the adult population with an artificial airway due to trauma, a medical condition or airway maintenance. Both have 15mm connectors for attachment to airway circuits, which are compatible with standard healthcare systems for use of humidification and/or ventilation equipment. Both, the subject and predicate devices provide a neck strap (tube holder) for use to secure the tracheostomy tube placement to the patient.

The surgical procedure is the same for BLUselect; anterior surgical approach of the patient's trachea anatomy. An invasive incision is made at the tracheal anatomy, in which a surgical stoma is created for the tracheostomy tube insertion. Both the subject and predicate devices are manufactured with a radio-opaque material, which assists the physician for device placement with x-ray.

The BLUselect trach tubes, subject device(s) and predicate devices are by prescription only, for single use and provided Ethylene Oxide (EO) sterile to the healthcare facility and/or end user.

The BLUselect inner cannula and predicate inner cannula are intended to be used with the tracheostomy tube and are by prescription only, for single-patient use and provided Ethylene Oxide (EO) sterile to the healthcare facility and/or end user. The inner cannula cleaning instructions allows for re-use with the same patient.

Principle of Operation

The *Smiths Medical Portex® BLUselect and BLUselect Suctionaid Tracheostomy Tubes and BLUselect Inner Cannula* 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.

A tracheotomy is a surgical procedure in which a direct airway is established by creating an opening in the anterior neck and placing a tracheostomy tube through the anterior neck into the trachea to secure the airway.

Summary of Performance Testing:

The *Smiths Portex® Medical BLUselect and BLUselect Suctionaid Tracheostomy Tubes and BLUselect Inner Cannula* incorporates the same indications for use, similar technological characteristics, including MRI conditional labeling and the similar tube sizes as the legally marketed primary predicate device the Blue Line Ultra Tracheostomy Tubes, K030381, 510(k) clearance issued August 27, 2003; Blue Line Ultra Suctionaid Tracheostomy Tube with reusable inner cannula, K030570; 510(k) clearance issued Sept 17, 2003. MRI Conditional labeling primary predicate device is the Bivona Tracheostomy Tubes, K083641; 510(k) clearance issued Feb 23, 2009.

Non-clinical testing of the components comprising each configuration of the subject devices *Smiths Medical Portex® BLUselect, BLUselect Suctionaid Tracheostomy Tubes and BLUselect Inner Cannula* were assessed and tested appropriately to design controls; i.e. design verification, design validations. The test results conclude the subject products are substantially equivalent to the predicate devices described herein (above). Testing listed below:

Smiths Medical Portex® BLUselect Tracheostomy Tubes / Inner Cannula:

- Bench Testing was conducted per ISO 5366:2016 to ensure the BLUselect devices meets the essential requirements for paediatric tracheostomy tubes.

- Bench Testing was conducted per ISO 5356-1[1]to ensure the BLUselect devices is compatible with breathing system connection via 15mm connector; which are used for standard anesthetic and respiratory equipment.

- Bench Testing was conducted per ISO 18190 to ensure the BLUselect devices is safe and effective when used as an airway device and/or equipment.

- Magnetic Resonance Environment use was assessed per SSTM F2052-15 and MRI Conditional marking per ASTM F2503 to ensure BLUselect devices are safe for Magnetic Resonance Imaging (MRI).

- Cleaning Instruction Validation for the BLUselect Inner Cannula was conducted per the FDA Guidance, AAMI TIR 30, AAMI TIR12 and AAMI TIR34. The inner cannula is a single-patient use and can be effectively cleaned for re-use with the IFU instructions.

- Tube External Maintenance instructions for the BLUselect device to remove secretions or debris from the external surfaces of the accessible portion of the device, will the device is *in-situ*. Instructions comply too the common practice in a healthcare or home care setting; similar to cleaning instructions of the predicate devices.

- Design Validation / Human Factors per ISO 62366 was conducted to ensure the subject device(s) performance is acceptable for its intended use.

- Sterilization/Microbiology Validation was conducted to ensure the subject device product sterility to the end user for ISO 11135, AAMI TIR28 and ISO 11747 is acceptable.

- Biocompatibility Assessment per ISO 10993-1 was conducted to ensure the subject devices materials are biocompatible and equivalent with the same base materials of the predicate devices. The following end-points were evaluated: cytotoxicity, sensitization, irritation, acute systemic toxicity, pyrogenicity, subchronic toxicity, genotoxicity, and implantation.

    - Patient Contacting Components

BLUselect Component(s)		Contact Type	Duration of Use
Tracheostomy Tube Components	15mm connector	Externally Communicating – Tissue	≤29 days, prolonged
	Tube with molded flange	Tube: Externally Communicating – Tissue Flange: Surface Device – Compromised Surface	≤29 days, prolonged
	Soft-seal cuff	Surface Device – Mucosal Membrane	≤29 days, prolonged
	Inflation line	Surface Device – Mucosal Membrane	≤29 days, prolonged

[1] ISO 5356 – Smiths complies with revision 2004 and 2015

BLUselect Component(s)		Contact Type	Duration of Use
	Pilot line	Surface Device – Intact Skin	≤29 days, prolonged
	Inflation line Valve assembly	Surface Device – Intact Skin	≤29 days, prolonged
	Suction line	Surface Device – Mucosal Membrane	≤29 days, prolonged
	Suction connector	Surface Device – Intact Skin	≤29 days, prolonged
	Valve guard	Surface Device – Intact Skin	≤29 days, prolonged
Inner Cannula		Externally Communicating – Tissue	≤29 days, prolonged

Substantial Equivalence

Smiths Medical considers the subject devices performance to be substantially equivalent to the predicate device(s), because these devices are intended for same patient population that require an artificial airway due to trauma, a medical condition and/or airway maintenance.

Subject Devices:

- *Smiths Medical Portex® BLUselect® Tracheostomy Tube*
- *Smiths Medical Portex® BLUselect® Suctionaid® Tracheostomy Tube*
- *Smiths Medical Portex® BLUselect® Tracheostomy Inner Cannula*

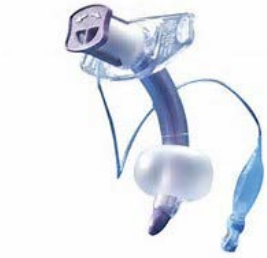
There are no significant differences in the intended use, mechanical and functional performance and functional scientific technology. Overall and including the difference in the material change for the tracheostomy tube, Smiths Medical demonstrations there are no new issues of safety and effectiveness are raised due to the similarities/differences between the subject and predicate/commercialized devices, as each are used to treat the same clinical condition and represent a similar/basic design concept.

Table 3 below provides a substantial equivalence summary of the subject device and predicate devices, including device pictures.

Table 3: Substantial Equivalence Summaries:

BLUselect / Suctionaid / Inner Cannula

Product Component	Subject Device BLUselect Tracheostomy Tube w/wo Suctionaid and Inner Cannula	Predicate Device K030570 Blue Line Ultra/Suctionaid	Compare
Product Code	BTO	BTO	Same
Product Classification	Class II	Class II	Same
Device Classification Name and 21 CFR	*Tracheostomy tube and tube cuff* § 868.5800	*Tracheostomy tube and tube cuff* § 868.5800	Same
Invasive or Non-Invasive	Surgically Invasive	Surgically Invasive	Same
Patient Population	Adults with average height, weight, and anthropometrics.	Adults with average height, weight, and anthropometrics.	Same
Intended Use	For use with patients that require an artificial airway due to trauma or medical condition.	For use with patients that require an artificial airway due to trauma or medical condition.	Same
Maximum Use	Recommended 29 Days	Recommended 29 Days	Same
Indications for Use Tracheostomy Tube	Smiths Medical Portex® BLUselect® and Suctionaid Tracheostomy Tube is indicated for airway maintenance of tracheostomised patients.	Portex® Blue Line Ultra® and Suctionaid Tracheostomy Tube is indicated for airway maintenance of tracheostomised patients.	Same
Indications for Use Suctionaid	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.	Portex® Blue Line Ultra® 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.	Same
Indications for Use Inner Cannula	The BLUselect® Inner Cannula is intended to be used with the Smiths Medical Portex® BLUselect® Tracheostomy Tube indicated for airway maintenance of tracheostomy patients.	Portex® Blue Line Ultra Tracheostomy Inner Cannula is intended to be used with the Smiths Medical Portex® Blue Line Ultra Tracheostomy Tube indicated for airway maintenance of tracheostomy patients. (not included in IFU)	Same
Functionality	Smiths Medical Portex® BLUselect® Tracheostomy Tube is intended for airway maintenance and is optionally available with a range of secondary features including cuff, Suctionaid®, and fenestrations in a size range from 6.0mm to 10.0mm for adult patients	Portex® Blue Line Ultra® Tracheostomy Tube is intended for airway maintenance and is optionally available with a range of secondary features including cuff, Suctionaid®, and fenestrations in a size range from 6.0mm to 10.0mm for adult patients	Same
Sterilization	Ethylene Oxide (EO) Sterile SAL 10^{-6} to End User	Ethylene Oxide (EO) Sterile SAL 10^{-6} to End User	Same

Product Component	Subject Device BLUselect Tracheostomy Tube w/wo Suctionaid and Inner Cannula	Predicate Device K030570 Blue Line Ultra/Suctionaid	Compare
Biocompatibility	Compatibility materials ISO 10993-1: 2009	Compatibility materials ISO 10993-1: 2009	Same
MRI Conditional	Yes	Yes	Same
Shelf Life	5-year shelf life intended	5-year shelf life	Same
Single Use Single Patient Use	Yes	Yes	Same
Environment of Use	Critical care settings, Acute care settings, Long term care facilities	Critical care settings, Acute care settings, Long term care facilities	Same
Home Care Use	Yes	Yes	Same
Tracheostomy Tube Materials (Flexible PVCs)	Main Tube Body: DEHT PVC Inflation Line: DEHT PVC Pilot Balloon: DEHT PVC Suction Line: DEHT PVC Cuff Bonding Cement: DEHT PVC All other materials of Construction are equivalent	Main Tube Body: DEHP PVC Inflation Line: DEHP PVC Pilot Balloon: DEHP PVC Suction Line: DEHP PVC Cuff Bonding Cement: DEHP PVC All other materials of Construction are equivalent	Different
Flange Marking Color Coding	Laser Marked Product Information with Vinyl Ink Printed Color Coding Band 	Clear Embossed Mark 	Different
Suctionaid feature	Available	Available	Same
Varied Components	Included	Included	Same
Inner Cannula	Included	Included	Same
Cleaning Instructions	Included	Included	Same
IFU	Included	Included	Same

Conclusion

Smiths Medical's evaluation concludes that the subject devices are substantially equivalent to the predicate device.