December 7, 2017

Smiths Medical ASD, Inc.
James Taufen
Director Regulatory Affairs
6000 Nathan Lane North
Minneapolis, Minnesota 55442

Re: K170720
Trade/Device Name: Portex Blue Line Ultra Paediatric Tracheosomy Tube
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube And Tube Cuff
Regulatory Class: Class II
Product Code: JOH
Dated: November 7, 2017
Received: November 8, 2017

Dear James Taufen:

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,

Tara A. 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

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)*

K170720

Device Name
Smiths Medical
Portex® Blue Line Ultra® Paediatric Tracheostomy Tube

Indications for Use *(Describe)*
Portex® Blue Line Ultra® Paediatric Tracheostomy Tubes are 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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"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	**510(k) SUMMARY** ***Portex®*** ***Blue Line Ultra®*** **Paediatric Tracheostomy Tube**

Date of Summary Preparation: December 5, 2017 - revised

Submitter:
Smiths Medical
6000 Nathan Lane
Minneapolis, MN 55442
USA

Establishment Registration Number: 3012307300 (Minneapolis)

Company Contact (Primary):
James Taufen
Director Regulatory Affairs
Email: james.taufen@smiths-medical.com
Office: 763-383-3174

Trade Name(s): Tracheostomy Tube, Paediatric

Device Names(s): *Portex® Blue Line Ultra®* Paediatric Tracheostomy Tube

Device Classification: Class II

Regulation Number and Product Code(s):
21 CFR § 868.5800/ JOH
Tracheostomy tube and tube cuff

Purpose

The purpose of this premarket notification Traditional 510(k) is to obtain FDA clearance of the *Portex® Blue Line Ultra® Paediatric Tracheostomy Tube* for pediatric patients requiring an artificial airway for airway maintenance.

Primary Predicate Device

The primary predicate device for this submission is the currently marketed *Smiths Medical Bivona Uncuffed Paediatric Tracheostomy Tube* listed below.

Primary Predicate Device Name	Product Code	FDA 510k Number Clearance Date
Bivona Uncuffed Pediatric Tracheostomy Tube (wire reinforced) *Original Applicant: Bivona Medical*	JOH 21 CFR § 868.5800	K912469 Cleared Jun 14, 1991

Additional Predicate Devices:

Additional Predicate Device Name	Product Code	FDA 510k Number Clearance Date
Shiley Neonatal, Pediatric, Pediatric Long Tracheostomy Tube Cuffless *Original Applicant: Covidien*	JOH 21 CFR § 868.5800	K122531 Cleared Oct 9, 2012

General Device Description:

The *Portex® Blue Line Ultra® Paediatric Tracheostomy Tube* (Blue Paeds) is designed for the paediatric population who require an artificial airway due to trauma or medical condition. It is indicated for patients who require prolonged intubation for mechanical ventilator support; cannot manage their airway secretions; or have an upper airway obstruction. The subject device package consists of a paediatric tracheostomy tube and cotton tape (neck strap) and a maximum recommended period of use is 29 days.

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

Indications for Use:

Product Name	FDA 501(k) or PMA Numbers and Product Codes	Indications For Use
Portex® Blue Line Ultra® Paediatric Tracheostomy Tube	JOH	Portex® Blue Line Ultra® Paediatric Tracheostomy Tubes are indicated for airway maintenance of tracheostomised patients

Summary of Technological Characteristics:

The subject device, *Portex® Blue Line Ultra® Paediatric Tracheostomy Tube (Blue Paeds)* shares the similar technological characteristics as their 510(k) cleared predicates, Bivona Paediatric Tracheostomy Tube and Shiley Cuffless Neonatal, Pediatric, Pediatric Long Tracheostomy Tube.

Product Characteristics	***Subject Device Smiths Medical* Blue Line Ultra Paediatric Trach Tubes**	**PRIMARY Predicate Device Bivona Pediatric Tracheostomy K912469**	**ADDITIONAL Predicate Device Shiley Neonatal, Pediatric K122531**	**Compare**
Product Code	JOH	JOH	JOH	Same
Patient Population	Paediatric	Paediatric	Paediatric	Same
Intended Use	Paediatric patients that require an artificial airway due to trauma or medical condition. Maximum recommended period of use 29 days.	Paediatric patients that require an artificial airway due to trauma or medical condition. Maximum recommended period of use 29 days.	This device is intended for use in providing tracheal access for airway management.	Same
Indications For Use	The Blue Line Pediatric Tracheostomy Tube is indicated for **airway maintenance** of tracheostomy patients	The Bivona tracheostomy tube is intended **for direct airway access** for a tracheostomised patient for up to 29 days. It may be reprocessed for single-patient use up to 5 times.	This device is intended for use in providing tracheal access for **airway management**	Similar
Single Patient Use	Single Use for Maximum 29 Days	Single Use for Maximum 29 Days	Single Use for Maximum 29 Days	Same
Environment of Use	The product shall be used in a clinical environment such as the pediatric critical care units of a hospital, non-critical care units of a hospital, long care facilities and home care.	The product shall be used in a clinical environment such as the neonatal, pediatric or critical care units of a hospital, non-critical care units of a hospital, long care facilities and home care.	The product shall be used in a clinical environment such as the neonatal, pediatric or critical care units of a hospital, non-critical care units of a hospital, long care facilities and home care.	Same
Design Product Angle	90 degrees	120 degrees	120 degrees	**Different**
Cuff on Tube	Uncuffed Pediatric Tracheostomy Tube	Uncuffed Pediatric Tracheostomy Tube	Uncuffed Pediatric Tracheostomy Tube	Same
Cleaning Instructions	Available in IFU	Available in IFU	Available in IFU	Same
Design by Standard	ISO 5366-3:2001 and ISO 5366: 2016	ISO 5366-3:2001	ISO 5366-3:2001	Same

Product Characteristics	***Subject Device Smiths Medical* Blue Line Ultra Paediatric Trach Tubes**	**PRIMARY Predicate Device Bivona Pediatric Tracheostomy K912469**	**ADDITIONAL Predicate Device Shiley Neonatal, Pediatric K122531**	**Compare**
Materials	Medical Grade Polyvinyl Chloride (PVC) Non-phthalate (DEHT) Plasticizer	Medical Grade Silicone Not Applicable	Medical Grade Polyvinyl Chloride (PVC) Non-phthalate Plasticizer	Same for PVC
View by X-Ray	Blue Line of radio-opaque material Barium-Sulphate	Reinforced radio-opaque material Wire	Constructed with radio-opaque material (IFU)	Same
Package contents	Tube Neck strap (Cotton Tape)	Tube Neck Strap Obturator Disconnect Wedge	Tube Neck Strap Obturator	Similar
Mechanical Connection	15mm connector for attachment to breathing systems / mechanical ventilation	15mm connector for attachment to breathing systems / mechanical ventilation	15mm connector to standard ventilation and anesthesia equipment	Same
Surgical Procedure	Anterior surgical approach of Trachea Anatomy	Anterior surgical approach of Trachea Anatomy	Anterior surgical approach of Trachea Anatomy	Same
Functionally	Provide patient an artificial airway due to trauma or medical condition; Insertion in a tracheotomy stoma; Neck strap used for secure device placement	Provide patient an artificial airway due to trauma or medical condition; Insertion in a tracheotomy stoma; Neck strap used for secure device placement	Provide patient an artificial airway in order to provide access to the patient's airway; Insertion in a tracheotomy stoma; Neck strap used for secure device placement	Same
Sterilization	Ethylene Oxide (EO) Sterile SAL 10^{-6} to End User	Ethylene Oxide (EO) Sterile SAL 10^{-6} to End User	Ethylene Oxide (EO) Sterile SAL 10^{-6} to End User	Same
Biocompatibility	Compatible materials ISO 10993-1:2009	Compatible materials ISO 10993-1:2009	Compatible materials ISO 10993-1:2009	Same
Shelf Life	5-year shelf life	5 years	Unknown	Same
Magnetic Resonance Image (MRI)	MRI Safe	MRI Conditional K083641	Unknown	Similar

Differences

The subject and predicate devices include the same overall design, and same range of sizes, with the only difference being the tube 90 degree curve angle. The risks associated with 90 degree curve design were mitigated through 1) ISO 5366-3 standard compliance testing according to requirements for paediatric tracheostomy tube, 2) material selection of thermosensitive material, and 3) human factor studies.

The BLU PAEDS device is manufactured with Polyvinyl Chloride (PVC) with non-phthalate plasticizer (DEHT) while the Bivona Paediatric Tube predicate device material is a medical grade silicone. These subject and primary predicate devices include the same intended use of 29 days for the pediatric patient population. The risk associated with prolonged exposure to new DEHT material was mitigated through successful ISO 10993 Standard testing demonstrating the material met all biocompatibility requirements for its intended use.

The BLUE PAEDS MRI-safe compatibility was verified according to ASTM F2503-13 through material analysis determining that the materials are nonconductive, nonmetallic and nonmagnetic. Bivona device is labelled as MRI-conditional due to a wire-reinforced tube. MRI labeling for Shiley is unknown.

Similarities

Both the subject device and predicate devices indications for use are similar because they are all for single-patient use and indicated for airway maintenance of tracheostomy patients. The only difference is the predicate, Bivona Pediatric, is a silicone tracheostomy tube and may be reprocessed for single-patient use up to 5 times.

Both the subject and predicate devices, 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 (cotton tape) for use to secure the tracheostomy tube placement to the patient. The subject device and predicate devices are prescribe by physician only, for single use and provided Ethylene Oxide (EO) sterile to the healthcare facility and/or end user.

The size of the tube needed depends on the age and size of the child. The inner diameter is the actual diameter of breathing room and is also the uniform standard classification system in use today. The outer diameter is the actual size of the tube. The size and configuration offering is noted below:

Size:	ID	OD	Length
3.0 mm	3.0 mm	4.2 mm	36 mm
3.5 mm	3.5 mm	4.9 mm	39 mm
4.0 mm	4.0 mm	5.5 mm	43 mm
4.5 mm	4.5 mm	6.2 mm	46 mm
5.0 mm	5.0 mm	6.9 mm	50 mm

The predicate devices include a 2.5 and 5.5mm. Inner Diameter (ID) is defined in ISO 5366-3 and ISO 5366, and all three devices have same ID. Outer Diameter (OD) nominal is not defined in ISO standard, each device design can define proper OD (and wall thickness) depends on corresponding material properties.

Summary of Performance Testing:

Non-clinical testing of the components comprising each configuration of the subject BLUE PAEDS were assessed and tested appropriately to design controls; i.e. design verification, design validations. The test results conclude the BLUE PAEDS to be substantially equivalent to the predicate devices described herein (above). Testing listed below:

- Bench Testing was conducted per ISO 5366-3 and ISO 5366:2016[1] to ensure the BLU PAEDS device meets the essential requirements for paediatric tracheostomy tubes.

- Bench Testing was conducted per ISO 5356-1[2] to ensure the subject device 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 evaluate the device for use as an airway device and/or equipment.

- Material Bench Testing was conducted to ensure the subject device materials met radiopacity; cleaning agents (solutions) compatibility, MRI compatibility and gas/vapor compatibility. The cleaning instructions for the subject device complies to 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* performance is acceptable for its intended use.

- Sterilization/Microbiology Validation was conducted to ensure product sterility to the end user for ISO 11135 and ISO 11747.

- Biocompatibility Assessment per ISO 10993-1 was conducted to ensure the subject device materials are biocompatible and equivalent with the same base materials of the Shiley predicate device.

Smiths Medical considers the subject device, *Portex® Blue Line Ultra® Paediatric Tracheostomy Tube* performance to be substantially equivalent to the predicate device(s), because these devices are intended for paediatric patients that require an artificial airway due to trauma, a medical condition and/or airway maintenance.

Smiths Medical demonstrated no different issues of safety and effectiveness were raised due to the similarities/differences between the subject device, *Portex® Blue Line Ultra® Paediatric Tracheostomy Tube,* and predicate/commercialized devices. Smiths Medical concludes the subject device is substantial equivalent for use in paediatric patients for the treatment of an artificial airway.

[1] ISO 5366:2016 exception is the 15mm connector ID (clause 6.3.1.2)

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