May 8, 2018

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

Re: K173912
Trade/Device Name: BLUperc® Percutaneous Dilation Tracheostomy Procedural Kit or Tray with or without BLUselect Tracheostomy Tube, and BLUgriggs® Percutaneous Dilation Tracheostomy Procedural Kit or Tray with BLUselect® Tracheostomy Tube with or without Forceps
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: Class II
Product Code: JOH
Dated: April 6, 2018
Received: April 9, 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,

Geeta K. Pamidimukkala -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173912

Device Name
Smiths Medical
BLUperc® Percutaneous Dilation Tracheostomy Procedural Kit or Tray with or without BLUselect® Tracheostomy Tube

Indications for Use *(Describe)*
Controlled, elective, subcricoid percutaneous insertion of a tracheostomy tube for airway management using a Seldinger guidewire dilation technique.

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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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)*

K173912

Device Name
Smiths Medical
BLUgriggs® Percutaneous Dilation Tracheostomy Procedural Kit or Tray with BLUselect® Tracheostomy Tube with or without Forceps

Indications for Use *(Describe)*
Controlled, elective subcricoid percutaneous insertion of a tracheostomy tube for airway management using a Seldinger technique to guide the specially designed Guidewire Dilating Forceps into the trachea, which are then used to dilate the trachea.

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** ***BLUperc®, and BLUgriggs®*** *Percutaneous Dilation Tracheostomy Procedural Kit or Tray*

Date of Summary Preparation:	May 3, 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):	• *BLUperc® Percutaneous Dilation Tracheostomy Procedural Kit or Tray with or without BLUselect® Tracheostomy Tube* • *BLUgriggs® Percutaneous Dilation Tracheostomy Procedural Kit or Tray with BLUselect® Tracheostomy Tube with or without Forceps*
Device Classification:	Class II
Regulation Number/Name	21 CFR § 868.5800 Tracheostomy Tube and Tube Cuff
Product Code(s):	JOH

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:

- *BLUperc® Percutaneous Dilation Tracheostomy Procedural Kit or Tray with or without BLUselect® Tracheostomy Tube*
- *BLUgriggs® Percutaneous Dilation Tracheostomy Procedural Kit or Tray with BLUselect® Tracheostomy Tube with or without Forceps*

Predicate Device for BLUperc® and BLUgriggs® PDT:

Information for the predicate device is provided in the table below for the subject devices, *BLUperc® and BLUgriggs® PDT.*

Primary Predicate: BLUperc® and BLUgriggs® PDT kits or trays

Primary Predicate Device Name	FDA 510(k) Number and Clearance Date	Classification	Primary Code
UltraPerc Percutaneous Dilation Kit *with Single Stage Dilator , Blue Line Ultra Tracheostomy Tube and Introducer*	K041348 July 13, 2004 *Original Applicant: Smiths Medical*	Class II	JOH 21 CFR 868.5800

Additional Predicates: BLUperc and BLUgriggs PDT kits or trays

Additional Predicate Device Name	FDA 510(k) Number and Clearance Date	Classification	Product Code
Portex Percutaneous Tracheostomy Kit	K060945 Jun 19, 2006 *Original Applicant: Smiths Medical*	Class II	BTO 21 CFR 868.5800

Reference Device: BLUperc and BLUgriggs PDT kits or trays

Reference Device Name	FDA 510(k) Number and Clearance Date	Classification	Primary Code
Percutaneous Dilation Kit with Single Stage Dilator and Soft Introducer for Sizes 7, 8, & 9 mm Tubes Only, without Tracheostomy Tubes	K040014 Feb 13, 2004 *Original Applicant: Portex Limited*	Class II	JOH 21 CFR 868.5800

General Device Description for BLUperc® and BLUgriggs®

The BLUperc® and BLUgriggs® Percutaneous Dilation Tracheostomy Tube Kits or Trays aid in the tracheostomy tube surgical procedure for adult patients; designed to aid adult patients

requiring an artificial breathing airway due to trauma, medical condition and/or for airway maintenance. The tracheostomy tubes (kits or trays) maximum recommended period of use is 29 days. The kit or tray contains all the proprietary procedural components to support tracheostomy insertion, including the BLUselect tracheostomy tube for physician's ease during the clinical procedure flow.

The BLUperc and BLUgriggs PDT 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:

Smiths Medical Product Name	Indications For Use
BLUperc® Percutaneous Dilation Tracheostomy Procedural Kit or Tray with or without BLUselect® Tracheostomy Tube	Controlled, elective, subcricoid percutaneous insertion of a tracheostomy tube for airway management using a Seldinger guidewire dilation technique
BLUgriggs® Percutaneous Dilation Tracheostomy Procedural Kit or Tray with BLUselect® Tracheostomy Tube with or without Forceps	Controlled, elective subcricoid percutaneous insertion of a tracheostomy tube for airway management using a Seldinger technique to guide the specially designed Guidewire Dilating Forceps into the trachea, which are then used to dilate the trachea.

Principle of Operation

The *BLUperc and BLUgriggs Percutaneous Dilation Tracheostomy Tube Kits or Trays* aid in the tracheostomy tube surgical procedure because the kit or tray contains all the proprietary procedural components to support tracheostomy insertion, including the tracheostomy tube for physician's ease during the clinical procedure flow.

The *BLUperc Kits or Trays* are designed for the *Seldinger Tracheostomy Technique:* A modification of the surgical technique, termed the Percutaneous Dilation Tracheostomy (PDT) technique, allows the placement of a tracheostomy tube using the Seldinger technique. The PDT technique uses a dilator inserted over the guide wire into the trachea to dilate the skin, subcutaneous tissue and tracheal opening, to allow insertion of the tracheostomy tube.

The *BLUgriggs Kits or Trays* are designed for *Griggs Forceps Technique:* A modification to the PDT technique (above), instead of advancing the dilator over the guide wire, the Griggs Forceps technique uses closed forceps to advance into the trachea over the guide wire. The forceps are then opened to dissect the subcutaneous and tracheal tissue creating a hole, stoma, to allow easy placement of the tracheostomy tube.

Summary of Technological Characteristics:

The BLUperc and BLUgriggs PDT subject devices share the similar technological characteristics as their 510(k) cleared predicates, UltraPerc PDT kits or trays. 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, proprietary procedural components to support tracheostomy insertion, including a tracheostomy tube to enhance the healthcare clinical workflow. Both the subject PDT device and predicate PDT devices are available as "Kits" which do not contain medications and as "Trays" which do contain medications.

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 BLUperc and BLUgriggs regarding the percutaneous dilation tracheostomy kits or trays are designed to aid the physician (healthcare staff) ease during the clinical procedure flow.

- The *BLUperc Kits or Trays* are designed for the *Seldinger Tracheostomy Technique:* The Percutaneous Dilation Tracheostomy (PDT) Seldinger technique uses a dilator that dilates and expands the subcutaneous and tracheal tissue to allow insertion of the tracheostomy tube.
- The *BLUgriggs Kits or Trays* are designed for *Griggs Forceps Technique:* A modification to the PDT technique (above); the Griggs Forceps technique uses a forceps that has a channel for the guide wire used in the PDT technique.

The BLUperc and BLUgriggs (PDT) 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.

Summary of Performance Testing:

The *BLUperc and BLUgriggs PDT Kits and Trays* incorporates the same indications for use, similar technological characteristics, including similar propriety components for the same surgical procedures (*Seldinger (PDT) and Griggs Forceps Techniques*) as the legally marketed primary predicate device the Percutaneous Dilation Tracheostomy Kit with Single Stage Dilator, Soft Introducer Blue Line Ultra Tracheostomy Tubes, K040014, 510(k) clearance issued Feb 13, 2004; Portex "UltraPerc" Percutaneous Dilation Tracheostomy Kit, K041348; 510(k) clearance issued July 13, 2004 and the Portex Percutaneous Tracheostomy Kit; K060945, 510(k) clearance issued July 19, 2006.

Non-clinical testing of the components comprising each configuration of the subject devices *BLUperc and BLUgriggs PDT Kits or Trays* 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:

- Bench Testing was conducted on applicable components of the BLUperc and BLUgriggs PDT Kits or Trays to ensure they met the required specifications for performance and functionality.

- Packaging Validation was conducted per ISO 11607 for the BLUperc and BLUgriggs PDT Kits and Trays to ensure the packaging system meets requirements and maintains the sterile barrier.

- 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 11737 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.

BLUperc / BLUgriggs Component(s)	Patient Contacting Type	Duration
Gauze Sponges	Surface Device, Breached Skin; Limited (Transient)	≤24 hours, limited
Curved Hemostat Forceps	Surface Device, Breached Skin; Limited (Transient)	≤24 hours, limited
Hypodermic Needle(s)	Surface Device, Breached Skin; Limited (Transient)	≤24 hours, limited
Griggs Forceps	Externally Communicating, Tissue; Limited (Transient)	≤24 hours, limited
14 FR Short Dilator	Externally Communicating, Tissue; Limited (Transient)	≤24 hours, limited
Dedicated Introducer	Externally Communicating, Tissue; Limited (Transient)	≤24 hours, limited
Obturator	Externally Communicating, Tissue; Limited (Transient)	≤24 hours, limited
Fenestrated Drape	Surface Device, Intact Skin; Limited	≤24 hours, limited
Split Tracheostomy Dressing	Surface Device, Breached Skin; Limited	≤24 hours, limited
Syringes	Surface Device, Breached Skin; Limited	≤24 hours, limited
Introducer Cannula & Needle Assembly	Externally Communicating, Tissue; Limited	≤24 hours, limited
J-tip Guidewire	Externally Communicating, Tissue; Limited	≤24 hours, limited
PEEP Keep Swivel Adaptor	Breathing Gas Pathway; Indirect Externally Communicating, Tissue; Limited	≤24 hours, limited
Tracheostomy Tube Holder with Brush (Neck strap)	Surface Device, Intact Skin; Prolonged	≤29 Day, prolonged
2/0 (3.0 metric) Polypropylene sutures	Surface Device, Breached Skin; Prolonged	≤29 Day, prolonged
Single Stage Dilator	Externally Communicating, Tissue; Limited (Transient)	≤24 hours, limited
Guiding Catheter	Externally Communicating, Tissue; Limited (Transient)	≤24 hours, limited
Soft Introducer	Externally Communicating, Tissue; Limited (Transient)	≤24 hours, limited
ChloraPrep Applicators	Surface Device, Intact Skin; Limited (Transient)	≤24 hours, limited
Filter Straw	Surface Device, Breached Skin; Limited (Transient)	≤24 hours, limited
Introducer Needle(s)	Externally Communicating, Tissue; Limited (Transient)	≤24 hours, limited
Safety Scalpel	Externally Communicating, Tissue; Limited (Transient)	≤24 hours, limited
BLUselect Tracheostomy Tube	Externally Communicating, Tissue; Prolonged	≤29 Day, prolonged

BLUperc / BLUgriggs Component(s)	Patient Contacting Type	Duration
BLUselect Inner Cannula	Externally Communicating, Tissue; Prolonged	≤29 Day, prolonged
Lubricating Jelly	Off-the-shelf drug	Off-the-shelf drug
5mL Lidocaine & Epinephrine 1.5%	Off-the-shelf drug	Off-the-shelf drug
Single handed guidewire feeder	No Patient Contact	No Patient Contact
Nozzle	No Patient Contact	No Patient Contact
Needle Driver	No Patient Contact	No Patient Contact
Needle Safety Device	No Patient Contact	No Patient Contact
Disconnection Wedge	No Patient Contact	No Patient Contact
Vacuum Control Valve	No Patient Contact	No Patient Contact
Patient Label	No Patient Contact	No Patient Contact
IFUs	No Patient Contact	No Patient Contact

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:

- *BLUperc® Percutaneous Dilation Tracheostomy Procedural Kit or Tray with or without BLUselect® Tracheostomy Tube*
- *BLUgriggs® Percutaneous Dilation Tracheostomy Procedural Kit or Tray with BLUselect® Tracheostomy Tube with or without Forceps*

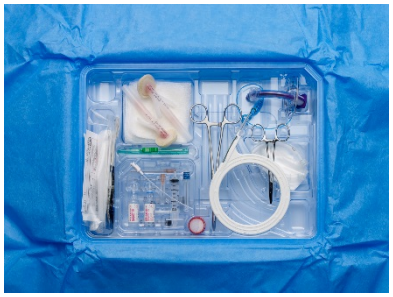
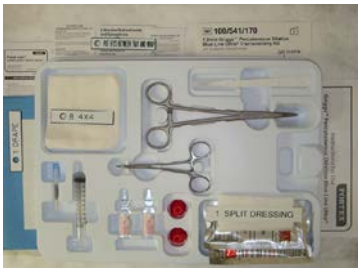
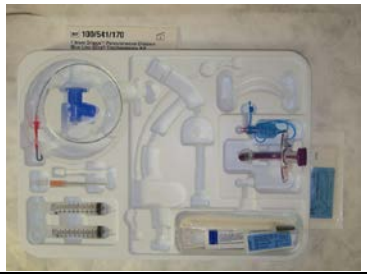
There are no significant differences in the intended use, mechanical and functional performance and functional scientific technology. Overall and including the difference in the proposed subject kits or trays, Smiths Medical demonstrates there are no different questions of safety and effectiveness raised 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 below provides a substantial equivalence summary of the subject device and predicate devices, including device pictures.

Substantial Equivalence Summaries:

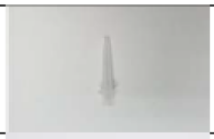
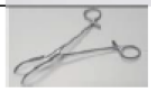
BLUperc and BLUgriggs PDT compared to UltraPerc and Portex PDT Kit

Product Component	Subject Device BLUperc and BLUgriggs	Primary Predicate: K041348 Additional Predicate: K060945 Reference Device: K040014	Compare
Product Code	JOH	JOH	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
Indications for Use	**BLUperc**: Controlled, elective, subcricoid percutaneous insertion of a tracheostomy tube for airway management using a Seldinger guidewire dilation technique.	**K041348**: Create a percutaneous dilational tracheostomy using guidewire dilator/s and components of these kits that allow for tracheal access for airway management for use in adults only.	
		K040014: Create a percutaneous dilational tracheostomy using guidewire, single stage dilator and components of this product which allows for tracheal access for airway management.	Same
	BLUgriggs: Controlled, elective subcricoid percutaneous insertion of a tracheostomy tube for airway management using a Seldinger technique to guide the specially designed Guidewire Dilating Forceps into the trachea, which are then used to dilate the trachea.	**K060945**: Create a percutaneous dilational tracheostomy using guidewire, pre-dilator, forceps, and components of this product which allows for tracheal access for airway management.	
Functionality	A percutaneous dilation tracheostomy procedural Kit or Tray that allows the percutaneous insertion of a tracheostomy tube using a one stage circumferential dilational Seldinger guidewire technique or The Griggs Forceps technique uses a forceps that has a channel for the guide wire used in the PDT technique	A percutaneous dilation tracheostomy procedural Kit or Tray that allows the percutaneous insertion of a tracheostomy tube using a one stage circumferential dilational Seldinger guidewire technique or The Griggs Forceps technique uses a forceps that has a channel for the guide wire used in the PDT technique	Same
Sterilization	Ethylene Oxide (EO) Sterile SAL 10^{-6} to End User	Ethylene Oxide (EO) Sterile SAL 10^{-6} to End User	Same
Biocompatibility	Compatibility materials	Compatibility materials	Same

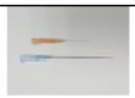
Product Component	Subject Device BLUperc and BLUgriggs	Primary Predicate: K041348 Additional Predicate: K060945 Reference Device: K040014	Compare
	ISO 10993-1: 2009	ISO 10993-1: 2009	
Shelf Life	3-year shelf life intended	5-year shelf life intended	Same
Single Patient Use	Yes	Yes	Same
Environment of Use	Hospital environments only	Hospital environments only	Same
BLUperc Tray Product Figure/ Picture **BLUperc Kit** Product Figure/ Picture **BLUgriggs Tray** Product Figure/ Picture **BLUgriggs Kit** Product Figure/ Picture	Various Components 	Various Components  	Similar
Trach Tube	Included	Included	Same
Varied Components	Included	Included	Same
Inner Cannula	Included	Included	Same
IFU	Included	Included	Same

Newly included Components of the Subject Device Kit/Tray

Component Table

Component	Picture	Description	US FDA Classification	510(K) Number	Rationale
Lubricating Jelly Sachet		A lubricating substance used to coat and lubricate the outer diameter and cuff of the tracheostomy tube and the obturator.	876.1500 Class II FHX	K912132	This device was identified as a kit component in the predicate kit K041348. It is referenced on pg. 234 of K041348.
Split Tracheostomy Dressing		A dressing that is pre-cut to fit around the tracheostomy tube. It is placed between the skin and the tracheostomy tube flange after the tracheostomy tube is positioned in the stoma.	878.4014 Class I NAB	Exempt	This device was identified as a kit component in the predicate kit K041348. It is referenced on pg. 173 of K041348.
Single Handed Guidewire Feeder Nozzle	 	A clear polypropylene nozzle which is used to Straightens the J-tip guidewire and attaches to the single hand guidewire feeder and introducer needle/cannula such that the guidewire may be passed into the trachea.	Not a medical device	N/A	This component should have been included with the Single Guidewire Feeder in the original table of this premarket notification (878.4800, Class 1, FZX, Exempt).
Curved Hemostat Forceps		A pair of large stainless steel forceps with curved tips used to dilate the trachea.	878.4800 Class I HTD	Exempt	This medical device is Exempt.
Suture		Polypropylene thread with curved needles on the ends used to sew the tracheostomy tube to the patient in order to prevent the tube from being dislodged	878.5010 Class II GAW	K001185	The device was previously cleared in K001185, 06/23/2000 by CP Medical. This device was not identified as a component in the predicate kit(s). This device is part of the proposed kit.

Component Table

Component	Picture	Description	US FDA Classification	510(K) Number	Rationale
Needle Safety Device		A cylindrical tube filled with foam used to store sharps safely after use	Not a medical device	N/A	This component is not a medical device. This component is being introduced in the proposed kit as a convenience component.
PEEP Keep Swivel Adaptor		An adaptor that introduces an additional entrance port to the airway circuit. Allows for the passage of a bronchoscope into the trachea without losing ventilating capabilities.	868.5810 Class I BZA	Exempt	This medical device is Exempt. As a note: This device was identified as a kit component in the predicate kit K041348. It is referenced on pg. 173 of K041348.
Vacuum Control Valve		A valve that introduces a port into a vacuum system line, provides clinicians with the ability to vacuum up fluids at their discretion. When the port is occluded, suction occurs through the vacuum line.	868.6810 Class I OFS	Exempt	This medical device is Exempt. This device was originally identified as a kit component in the predicate kit K041348. It is referenced on pg. 62 of K060945.
Povidone Iodine		An antiseptic used for skin disinfection before and after surgery	Not a medical device	N/A	Povidone Iodine is a drug classified under Prep Component. The predicate component is identified by Iodophor PVP-NDC 552380-3101-5. This component will not be included in the proposed kit.
Hypodermic Needle 22GX1.5"		Two needles with different lengths and gauges, Used to deliver drugs subcutaneously.	880.5570 Class II FMI	K854547	This device was cleared in K854547, 02/04/1986 by Sherwood Medical.

Conclusion

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

Subject Devices	Predicates	510(k)
BLUperc PDT BLUgriggs PDT	Primary Predicate UltraPerc PDT	K041348
	Additional Predicate Portex Percutaneous Tracheostomy Kit	K060945
	Reference Device Percutaneous Dilation Kit with Single Stage Dilator and Soft Introducer	K040014