June 1, 2020

Covidien
Stacy Barton
Senior Regulatory Affairs Specialist
6135 Gunbarrel Ave
Boulder, Colorado 80301

Re: K193077
Trade/Device Name: Shiley Adult Flexible Evac Tracheostomy Tube with TaperGuard Cuff
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube And Tube Cuff
Regulatory Class: Class II
Product Code: JOH, BTO
Dated: April 24, 2020
Received: April 27, 2020

Dear Stacy Barton:

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 ENT, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193077

Device Name

Shiley™ Adult Flexible Evac Tracheostomy Tube with TaperGuard™ Cuff

Indications for Use *(Describe)*

Provide tracheal access for airway management and subglottic secretion management in adult patients. It is also intended for use with percutaneous dilatational tracheotomy (PDT) procedures.

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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510(k) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a 510(k) Summary for the Shiley™ Adult Flexible Evac Tracheostomy Tube with TaperGuard™ Cuff.

I Submitter

Submitted By:

Covidien
6135 Gunbarrel Avenue
Boulder, CO 80301

Date:

May 22, 2020

Contact Person:

Stacy Barton
Sr. Regulatory Affairs Specialist
(720) 376-0061

II Device

Proprietary Name:

Shiley™ Adult Flexible Evac Tracheostomy Tube with TaperGuard™ Cuff

Common Name:

Tracheostomy Tube & Tube Cuff

Device Classification Regulation:

21 CFR 868.5800 – Class II

Device Product Code & Panel:

JOH, BTO

III Predicate Devices

Smiths Medical Portex® BLUselect® Suctionaid® Tracheostomy Tube (K173384)

Shiley™ Adult Flexible Tracheostomy Tube Cuffless or with TaperGuard™ Cuff, Reusable Inner Cannula (RIC) (K150844)

Reference Devices

Portex Blue Line Ultra Suctionaid Tracheostomy Tube (K030570)

Shiley™ Adult Flexible Tracheostomy Tube Cuffless or with TaperGuard™ Cuff, Disposable Inner Cannula (DIC) (K142296)

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Reference Devices (continued): Shiley™ (formally Mallinckrodt) Oral/Nasal Tracheal Tube Cuffless, Non-DEHP, Murphy Eye (K151381)

IV Device Description

The subject device is a single patient use tracheostomy tube that features an outer cannula with a radiopaque line along its length and a standard 15mm connector for direct connection to standard ventilation and anesthesia equipment. It has an integrated evac suction line in the outer cannula for suctioning of subglottic secretions that may pool above the cuff. It is available in three configurations: single cannula (no inner cannula), disposable inner cannula (DIC) and single patient use reusable inner cannula (RIC).

V Indications for Use/Intended Use

The subject device is intended for use in providing tracheal access for airway management and subglottic secretion management in adult patients and is also intended for use with percutaneous dilatational tracheotomy (PDT) procedures.

VI Technological Characteristics Comparison

The subject device and the predicate devices have similar technological characteristics: outer cannula; single patient use inner cannula; 15mm connector; flange; cuff; inflation line; and evac suction line.

The subject and predicate devices are made with similar material (PVC with DEHT plasticizer). The subject device inner cannula is made with polyethylene; the reusable inner cannula material is identical to the RIC of predicate K150844. A comparison table has been provided on the next page.

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	SUBJECT DEVICE	PREDICATE DEVICES		Comparison
	Shiley™ Adult Flexible Evac Tracheostomy Tube with TaperGuard™ Cuff (Single Cannula, DIC, RIC) K193077	**Portex® BLUSelect® Suctionaid® Tracheostomy Tube K173384**	**Shiley™ Adult Flexible Tracheostomy Tube, Reusable Inner Cannula (RIC) K150844**	
INDICATIONS FOR USE				
Intended Use	Providing tracheal access for airway management and subglottic secretion management for adult patients. Also intended for use with percutaneous dilatational tracheotomy (PDT) procedures.	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.	Providing tracheal access for airway management. Also intended for use with Percutaneous Dilatational Tracheotomy (PDT) procedures.	**Similar to K173384** **Similar to K150844**
Patient Population	Adults	Adults	Adults	**Same**
Environment of Use	Hospitals, long-term care facilities	Critical care settings, acute care settings, long term care facilities, and for home use	Hospitals, long-term care facilities, home care	**Similar to K173384** **Similar to K150844**
Use	Single patient	Single Patient	Single patient	**Same**
TECHNOLOGICAL CHARACTERISTICS				
MRI compatibility	Conditional	Conditional	N/A	**Same[1] as K173384**
PDT compatibility	Yes	No	Yes	**Same as K150844**

[1] Magnetic Resonance Environment use was assessed per ASTM F2052-15 (Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment) and MRI Conditional labeling according to ASTM F2503 (Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment) ensures safe use in Magnetic Resonance Environment

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Radiopaque	Yes	Yes	Yes	**Same**
Inner Cannula	Included	Included	Included	**Same**[2]
Sterilization	Ethylene oxide (SAL 10^{-6})	Ethylene oxide (SAL 10^{-6})	Ethylene oxide (SAL 10^{-6})	**Same**
Shelf Life	5 Years	5 Years	5 Years	**Same**
Size Range	6.5mm – 9.0mm, 10mm	6.0mm – 10mm	6.5mm – 9.0mm, 10mm	**Similar to K173384** **Same as K150844**
Connector	Standard 15mm connector	Standard 15mm connector	Standard 15mm connector	**Same**
MATERIALS (patient contact)				
Outer Cannula	PVC with DEHT plasticizer	DEHT PVC	PVC with DEHT plasticizer	**Similar to K173384** **Similar to K150844**
Inner Cannula	• Reusable: High density polyethylene • Disposable: Low density polyethylene	DEHT PVC	• Reusable: High density polyethylene	
Flange	PVC with DEHT plasticizer	DEHT PVC	PVC with DEHT plasticizer	
15mm Connector	Polymethylpentene	DEHT PVC	Polymethylpentene	
Cuff	PVC with DEHT plasticizer	DEHT PVC	PVC with DEHT plasticizer (cuffed configuration only)	
Evac Suction lumen; Yellow Connector/Cap	PVC with ATBC plasticizer; High Density Polyethylene	DEHT PVC	N/A	

[2] The subject device offers single cannula or inner cannula (RIC or DIC) configurations. The inner cannula cleaning instructions allow for re-use with the same patient (RIC configuration) and were validated according to AAMI TIR 30 (A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices).

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PERFORMANCE SPECIFICATIONS				
Device Design	ISO 5366, ISO 18190	ISO 5366, ISO 18190	ISO 5366	**Same as K173384** **Similar to K150844**

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VII Performance Data

The following performance testing was performed in support of the substantial equivalence determination:

Biocompatibility testing

The biocompatibility evaluation was conducted in accordance with FDA Guidance "*Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'*" May 1, 1995, and International Standard ISO 10993-1 "*Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process*," recognized by FDA.

Testing included cytotoxicity, sensitization, irritation, acute systemic toxicity, genotoxicity, subchronic toxicity implantation, chemical characterization, and risk assessment. The subject device met all biocompatibility requirements for its intended use.

Sterilization and Packaging Validation

The subject device is provided sterile via ethylene oxide sterilization and was validated to ensure sterility in accordance with ISO 11135-1 and ISO 10993-7. A packaging validation was conducted accordance with ISO 11607-1. The reusable inner cannula cleaning validation was performed in accordance with the AAMI TIR30:2011.

Bench Testing

Bench testing on the subject device was conducted in accordance with ISO 5366, ISO 5361, ISO 5356-1 and ISO 18190. In addition, internal bench testing was conducted to assess cuff performance, suction performance and evac lumen patency.

MRI Testing

MRI safety and compatibility testing and MR compatibility labeling for the subject devices comply with FDA guidance "*Establishing Safety and Compatibility of Passive Implants in the MR Environment*", and ASTM F2503-13.

Human Factors Testing

Human Factors testing was conducted in a simulated environment with 15 participants in accordance with FDA Guidance 1757 *Applying Human Factors and Usability Engineering to Medical Devices*.

VIII Substantial Equivalence

Intended Use

The subject device and predicate devices share similar intended uses. The subject device provides tracheal access for airway management and subglottic secretion management in adult patients while the predicate K173384 is for airway maintenance of tracheostomised patients and the aspiration of contaminated mucous and subglottic secretions that collect and build up between the tracheostomy tube cuff and the glottis.

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Additionally, the subject device is also intended for use with percutaneous dilatational tracheotomy (PDT) procedures. PDT is an alternative to the surgical placement of a tracheostomy tube and has been shown to be cost-effective and safe. (Najmuddin et al, 2014)[3]. The subject device is designed with a tapered tube tip identical to that of the predicate K150844 and the reference device K142296. PDT procedure compatibility does not impact the safety or effectiveness of the subject device.

Technological Characteristics

All patient contacting components of the subject and predicate devices are made with similar materials and plasticizer (PVC with DEHT). The inner cannulas of the subject device are made of polyethylene, and the material of the reusable inner cannula is identical to the RIC of predicate K150844, whereas the inner cannula of predicate K173384 is made of PVC with DEHT.

Both the subject and predicate devices comply with ISO 10993 for material biocompatibility and bench testing on the subject device was conducted per ISO 5366, ISO 5356-1, ISO 5361 and ISO 18190.

Reference Devices

This summary table presents legally marketed reference devices which:

- support the substantial equivalence determination of the subject device with the predicate devices
- share design, materials, and technological characteristics with the subject device

Name	FDA 510(k) Number and Clearance Date	FDA Product Code	Relevance
Portex Blue Line Ultra Suctionaid Tracheostomy Tube	K030570	BTO	Substantially equivalent to Predicate Device, K173384
Shiley™ Adult Flexible Tracheostomy Tube Cuffless or with TaperGuard™ Cuff, Disposable Inner Cannula (DIC)	K142296	JOH	Same design platform and similar materials as Subject Device, K193077
Shiley™ (formally Mallinckrodt) Oral/Nasal Tracheal Tube Cuffless, Non-DEHP, Murphy Eye	K151381	BTR	Same material as Subject Device, K193077

[3] Ahmad, Ali, Najmuddin, Asif, Hussain, Kashif, … A., A. (2014, September 15). Timing of Tracheotomy in Mechanically Ventilated Critically Ill Morbidly Obese Patients. Retrieved from https://www.hindawi.com/journals/ccrp/2014/840638/

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Clinical Evidence

N/A – Clinical evidence was not necessary to show substantial equivalence.

IX Conclusion

Substantial equivalence of the subject device is shown through performance testing as stated in the submission. The subject and predicate devices have similar indications, size ranges, intended use, environment of use, and patient population. No new questions of safety and effectiveness have been raised. From the evidence presented in the Premarket Notification, the subject device can be considered substantially equivalent to the predicate devices.

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