January 10, 2020

Salter Labs, Inc.
% Paul Dryden
Consultant
Salter Labs
2365 Camino Vida Roble
Carlsbad, California 92011

Re: K190878
Trade/Device Name: Salter Labs Trach-Vac Endotracheal Tube (SFTVPU) Subglottic Suction Tube with Salter Flex-Tip and Salter Thin Cuff
Salter Labs Trach-Vac Endotracheal Tube (SFTVVC) Subglottic Suction Tube with Salter Flex-Tip and Salter ThinCuff
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: December 10, 2019
Received: December 12, 2019

Dear Paul Dryden:

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)*

K190878

Device Name

Salter Labs Trach-Vac Endotracheal Tube (SFTVPU) Subglottic Suction Tube with Salter Flex-Tip™ and Salter ThinCuff ™
and
Salter Labs Trach-Vac Endotracheal Tube (SFTVVC) Subglottic Suction Tube with Salter Flex-Tip™ and Salter ThinCuff™

Indications for Use *(Describe)*

The Salter Labs Trach-Vac endotracheal tubes are indicated for nasal or oral intubation of the trachea for anesthesia and airway management, including mechanical ventilation and suctioning of accumulated subglottic secretions in the trachea of adult patients.

Type of Use *(Select one or both, as applicable)*

XX 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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Submission Correspondent: Paul Dryden, Consultant
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Proprietary or Trade Name:

Salter Labs Trach- Vac Endotracheal Tube (SFTVPU) Subglottic Suction Tube with Salter Flex-Tip™ and Salter ThinCuff ™

and

Salter Labs Trach- Vac Endotracheal Tube (SFTVVC) Subglottic Suction Tube with Salter Flex-Tip™ and Salter ThinCuff ™

Common/Usual Name: Tracheal Tube (w and w/o connector)

Classification Name: BTR – tube, tracheal (w/wo connector)
21CFR 868.5730, Class II

Predicate Device: K110269 - Well Lead Endotracheal Tube with Evacuation Lumen

Reference Device: K100546 - Parker ET Tube with Flex Tip

Device Description:
The Salter Labs Trach-Vac Endotracheal Tube (SFTVPU) Subglottic Suction Tube with Salter Flex-Tip™ and Salter ThinCuff ™ (polyurethane).

The Salter Labs Trach-Vac Endotracheal Tube (SFTVPU) Subglottic Suction Tube with Salter Flex-Tip™ and Salter ThinCuff ™ (6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 mm ID) are cuffed, sterile, single-use devices supplied with a standard 15mm conical connector. It is made of primarily of polyvinylchloride with a polyurethane (PU) cuff. In addition to the main lumen, the tube has a separate cuff inflation line and Evac lumen which has a dorsal opening above the cuff. A capped luer-style connection tube allows access to the separate lumen, enabling the health care professional to apply the suction to remove patient secretions. The tube incorporates a Magill curve, a hooded tip with two Murphy Eyes and a radiopaque line over the full length of the tube to assist in radiographic visualization.

The Salter Labs Trach-Vac Endotracheal Tube (SFTVVC) Subglottic Suction Tube with Salter Flex-Tip™ and Salter ThinCuff ™ (polyvinylchloride).

The Salter Labs Trach-Vac Endotracheal Tube (SFTVVC) Subglottic Suction Tube with Salter Flex-Tip™ and Salter ThinCuff ™ (6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 mm ID) are cuffed, sterile, single-use devices supplied with a standard 15mm conical connector. The tubing is made of primarily of polyvinylchloride (PVC) with a PVC cuff. In addition to the main lumen, the tube has a separate cuff inflation line and Evac lumen which has a dorsal opening above the cuff. A capped luer-style connection tube allows access to the separate lumen, enabling the health care professional to apply the suction to remove patient secretions. The tube incorporates

a Magill curve, a hooded tip with two Murphy Eyes and a radiopaque line over the full length of the tube to assist in radiographic visualization in the trachea after they pass through the vocal cords.

Indications for Use:
The Salter Labs Trach-Vac Endotracheal Tubes are indicated for nasal or oral intubation of the trachea for anesthesia and airway management, including mechanical ventilation and suctioning of accumulated subglottic secretions in the trachea of adult patients.

Device Comparison

Table 1 compares the subject device to the predicate

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Table 1 – Comparison of Proposed vs. Predicate Device

Specifications	**Predicate K110269** Well Lead Endotracheal Tube with Evacuation Lumen	**Subject device** Salter Labs Cuffed Trach-Vac Flex Tip ET Tube	Changes
Device Use & General Characteristics			
Regulation	21 CFR 868.5730	21 CFR 868.5730	Same
Class name	Tube, Tracheal (w/wo connector)	Tube, Tracheal (w/wo connector)	Same
Product code	73 BTR	73 BTR	Same
Intended Use	The Well Lead Endotracheal Tube with Evacuation Lumen is intended for Oral intubation and drainage of the subglottic space for airway management.	The Salter Labs Trach-Vac Endotracheal Tube Subglottic Suction Tube with Salter Flex-Tip™ and Salter ThinCuff ™ is indicated for airway management by oral intubation during mechanical ventilation and anesthesia including the capability to aid in the removal of Subglottic secretions.	Similar with details related to the tip design
Target Patient Population	The device is indicated for patients who require airway management via an endotracheal tube with subglottic suctioning.	The device is indicated for adult patients who require airway management via an endotracheal tube with subglottic suctioning.	Both devices are intended for adults, however the predicate wording did not include the specifics
Indications for use	The device is intended for oral intubation and drainage of the subglottic space for airway management.	The Salter Labs Trach-Vac Endotracheal Tubes are indicated for nasal or oral intubation of the trachea for anesthesia and airway management, including mechanical ventilation and suctioning of accumulated subglottic secretions in the trachea of adult patients.	Similar anatomical locations and population
Environment of use	Hospital, ICU	Professional use only: Intubation in the field (emergency medical services) or hospital environment, including ER, OR, and ICU.	The environments of use are similar. Use in the pre-hospital environment is also by trained providers
Principal of Operation and	a. The device is packaged individually and supplied sterile with a standard 15mm connector.	a. The device is packaged individually and supplied sterile with a standard 15mm connector.	Same

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Specifications	Predicate K110269 Well Lead Endotracheal Tube with Evacuation Lumen	Subject device Salter Labs Cuffed Trach-Vac Flex Tip ET Tube	Changes
Device Use & General Characteristics			
Mechanisms of Action	b. The endotracheal tube has a curved construction with primary lumen for patient ventilation. Two (2) narrower lumens within the primary wall are used for cuff inflation and subglottic evacuation (vacuum).	b. The endotracheal tube has a curved construction with primary lumen for patient ventilation. Two (2) narrower lumens within the primary wall are used for cuff inflation and subglottic evacuation (vacuum).	Same
	c. A low pressure, conformable cuff is inflated through the inflation line with pilot balloon using a standard 10cc syringe (air only) through a one-way check valve.	c. A low pressure, conformable cuff is inflated through the inflation line with pilot balloon using a standard 10cc syringe (air only) through a one-way check valve.	Same
	d. For evacuation of subglottic secretions, a separate suction line connects to standard hospital vacuum receptacles. Once properly intubated, subglottic secretions are evacuated through the suction line just superior to the cuff.	d. For evacuation of subglottic secretions, a separate suction line connects to standard hospital vacuum receptacles. Once properly intubated, subglottic secretions are evacuated through the suction line just superior to the cuff.	Same
	e. To facilitate proper positioning, the suction appendage and lumen line marker are radiopaque.	e. To facilitate proper positioning, the suction appendage and lumen line marker are radiopaque.	Same
Sterile or Non-Sterile	Sterile	Sterile	Same
Sterilization	Ethylene oxide	Ethylene oxide	Same
Use	Single patient/ single use only	Single patient / single use only	Same
Biocompatibility of Patient Contacting Materials			
ISO 10993-1	Externally Communicating / Tissue and Surface Contact / Mucosal Prolonged Duration of Use (> 24 hr, < 30 days)	Externally Communicating / Tissue and Surface Contact / Mucosal Prolonged Duration of Use (> 24 hr, < 30 days)	Same
Design			
Sizes (ID)	6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 mm	6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 mm	Same
Curve	Magill	Magill	Same
Murphy eye	Yes – 2 eyes	Yes – 2 eyes	Same
Connector (size/type)	15mm conical	15mm conical	Same
Suction port for	6% Male Luer connector	6% Male Luer connector	Same

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Specifications	Predicate K110269 Well Lead Endotracheal Tube with Evacuation Lumen	Subject device Salter Labs Cuffed Trach-Vac Flex Tip ET Tube	Changes
Device Use & General Characteristics			
removal of secretions that accumulate above the cuff			
Technological characteristics			
Technological characteristics	The design is based upon the cuffed Tube with the addition of a third lumen within the tube. It terminates above the cuff via a 'notch' (evacuation port) which enables the entrance (via suction) of secretions which have pooled above the cuff. Half way along the tube length the suction lumen is joined to a suction tube which is external to the main tube. The suction tube is joined to the suction lumen in a similar manner to that of the joint between the inflating tube and the inflating lumen. The distal end of the suction tube terminates in a capped Luer connector which can be connected to either the suction tubing or a syringe.	The design is based upon the cuffed Tube with the addition of a third lumen within the tube. It terminates above the cuff via a 'notch' (evacuation port) which enables the entrance (via suction) of secretions which have pooled above the cuff. Half way along the tube length the suction lumen is joined to a suction tube which is external to the main tube. The suction tube is joined to the suction lumen in a similar manner to that of the joint between the inflating tube and the inflating lumen. The distal end of the suction tube terminates in a capped Luer connector which can be connected to either the suction tubing or a syringe.	Same
Shelf life	5 years	5 years	Same

Differences
The differences between the Salter Labs Trach-Vac Endotracheal Tube Subglottic Suction Tube with Salter Flex-Tip™ and Salter ThinCuff ™ and the Well Lead Endotracheal Tube with Evacuation Lumen are below:

Table 2 – Differences between Proposed and Predicate

Features	K110269	Subject device
Tip design	Standard tip	The distal tip of the subject device includes a flexible tip, cleared in the reference device K100546, Parker Medical FLEX-TIP TRACHEAL TUBE. This reference device refers specifically to the design of the flexible tip at the distal end of the tube.

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Substantial Equivalence Discussion

The proposed Salter Labs Trach-Vac Endotracheal Tube Subglottic Suction Tube with Salter Flex-Tip™ and Salter ThinCuff ™ is viewed as substantially equivalent to the predicate device because:

Indications –
- Both are indicated for airway management by tracheal or oral intubation during mechanical ventilation and anesthesia including the capability to aid in the removal of subglottic secretions.

Patient Population –
- Both are intended for adult patients requiring airway management and may require secretion suctioning.

Environment of Use –
- For use in clinical settings by trained medical personnel

Technology and Principle Operation –
- Both are the same of a cuffed tube with a suctioning lumen.
- The proposed device included the Flex-tip which is similar to the Parker Flex Tip cleared under K100546.

Non-clinical Testing Summary -
We have performed tests appropriate for the proposed device. These tests include:

Biocompatibility of Materials –
The materials have been evaluated and tested in accordance with ISO 10993-1. Based upon ISO 10993-1 the subject device would be considered as having two types of patient contact.
- Externally Communicating / Tissue
  and
- Surface Contact / Mucosal
- Prolonged duration (> 24 hours and < 30 days)

The following testing was performed:
- ISO 10993-5 (2009) – Cytotoxicity
- ISO 10993-10 (2013) – Irritation / Intracutaneous Reactivity and Skin Sensitization
- ISO 10993-18 (2013) – Chemical Characterization with Toxicological Risk Assessment

Bench testing –
- Bench testing specific to
  - ISO 5361-1 (2016) – ET Tubes
  - ISO 80369-7 (2016) – Luer fitting
  - ISO 5356-1 (2016) – Conical Connectors – 15/22 mm
- Age testing

Clinical Testing Summary -
There was no clinical testing performed.

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Substantial Equivalence Conclusion

As established by description, data, and information contained within this 510(k), and as summarized in comparison table, the Salter Labs Trach-Vac Endotracheal Tube Subglottic Suction Tube with Salter Flex-Tip™ and Salter ThinCuff ™ is substantially equivalent to the predicate distributed commercially in the U.S. and worldwide. The Salter Labs Trach-Vac Endotracheal Tube Subglottic Suction Tube with Salter Flex-Tip™ and Salter ThinCuff ™ has the same Intended Use, Indications for Use nor does it alter the fundamental scientific technology, operation principles, design, or manufacturing process.