June 10, 2025

Vitaltec Corporation
% Ming-Yie Jan
Principal Consultant
RUSCERT Technology Co., Ltd.
8F., No. 187, Lequn 2nd Rd., Zhongshan Dist.
Taipei City, 10462
Taiwan

Re: K242921
Trade/Device Name: 5300600-5301000 Rota-Trach Disposable Standard Tracheostomy Tube, Cuffed, sizes 6.0-10.0mm; 5310600-5311000 Rota-Trach Disposable Standard Tracheostomy Tube, Cuffed, Fenestrated, sizes 6.0-10.0mm; 5400600-5401000 Rota-Trach Disposable Standard Tracheostomy Tube, Uncuff, sizes 6.0-10.0mm; 5410500-5411000 Rota-Trach Disposable Standard Tracheostomy Tube, Uncuff, Fenestrated, sizes 6.0-10.0mm
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube And Tube Cuff
Regulatory Class: Class II
Product Code: BTO
Dated: May 12, 2025
Received: May 14, 2025

Dear Ming-Yie Jan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242921

Device Name

5300600-5301000 Rota-Trach Disposable Standard Tracheostomy Tube, Cuffed, sizes 6.0-10.0mm
5310600-5311000 Rota-Trach Disposable Standard Tracheostomy Tube, Cuffed, Fenestrated, sizes 6.0-10.0mm
5400600-5401000 Rota-Trach Disposable Standard Tracheostomy Tube, Uncuff, sizes 6.0-10.0mm
5410500-5411000 Rota-Trach Disposable Standard Tracheostomy Tube, Uncuff, Fenestrated, sizes 6.0-10.0mm

Indications for Use *(Describe)*

Rota-Trach Disposable Standard Tracheostomy Tube is indicated for airway maintenance of tracheostomized 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

This 510 (K) summary is being submitted in accorndance with requirements of Title 21,CFR Section 807.92.

A. 510(k) NUMBER — K242921

B. DATE PREPARED — June 5th , 2025

C. SUBMITTER

Vitaltec Corporation
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D. CONTACT PERSON

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E. DEVICE

Proprietary Name:	5300600-5301000 Rota-Trach Disposable Standard Tracheostomy Tube, Cuffed, sizes 6.0-10.0mm 5310600-5311000 Rota-Trach Disposable Standard Tracheostomy Tube, Cuffed, Fenestrated, sizes 6.0-10.0mm 5400600-5401000 Rota-Trach Disposable Standard Tracheostomy Tube, Uncuff, sizes 6.0-10.0mm 5410500-5411000 Rota-Trach Disposable Standard Tracheostomy Tube, Uncuff, Fenestrated, sizes 6.0-10.0mm
Product Code:	BTO
Regulation Number:	21 CFR 868.5800
Regulation Name:	Tracheostomy Tube and Tube Cuff
Device Class:	Class II
Review Panel:	Anesthesiology

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F.	PRIMARY PREDICATE DEVICE	Proprietary Name:	Smiths Medical Portex® BLUselect® Tracheostomy Tube Smiths Medical Portex® BLUselect® Suctionaid® Tracheostomy Tube
		Product Code:	Smiths Medical
		Regulation Number:	BTO
		Regulation Name:	21 CFR 868.5800
		510(k) Number:	Tracheostomy Tube and Tube Cuff
		510(k) Submitter:	K173384
		Device Class:	Smiths Medical ADS, Inc.
		Review Panel:	Class II
			Anesthesiology

G. DEVICE DECRIPTION

Rota-Trach Disposable Standard Tracheostomy Tube is a respiratory device inserted into the patient's trachea through a stoma, making direct contact with the tracheal mucosal membrane tissue. It may be with or without a cuff attaching around the tube of the device. The design of the cuff could seal the space between the tube and the patient's trachea from inhaling undesired or foreign matters and for assistance of positive pressure ventilation.

H. INDICATIONS FOR USE

Rota-Trach Disposable Standard Tracheostomy Tube is indicated for airway maintenance of tracheostomized patients.

I. COMPARISON OF CHARACTERISTICS WITH THE PREDICATE DEVICES

Rota-Trach Disposable Standard Tracheostomy Tube and predicate device **(K173384)** are:

1. Same intended use/ indication(s) for use
2. Same intended population
3. Same mode of action
4. Same method of use
5. Same duration of use
6. Same environment of Use
7. Similar Biocompatibility evaluation endpoints
8. Different materials
9. Different shelf life

Based upon the information presented in this section, **Vitaltec Corporation** concludes that the **Rota-Trach Disposable Standard Tracheostomy Tube** is substantially

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equivalent to predicate devices in regard to indications for use, design, and technology, without raising any safety and efficacy risks or concerns.

Therefore, the difference in manufacturing process, base materials and properties do not raise concerns of the safety and effectiveness of the **Rota-Trach Disposable Standard Tracheostomy Tube**.

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B. Substantial Equivalence Comparison Table

Element of Comparison	**Proposed Device** Rota-Trach Disposable Standard Tracheostomy Tube	**Predicate Device:** K173384	**Comparison**
Product Code	BTO	BTO	Same
Indications for Use	Rota-Trach Disposable Standard Tracheostomy Tube is indicated for airway maintenance of tracheostomized patients.	Smiths Medical Portex® BLUselect® Tracheostomy Tube is indicated for airway maintenance of tracheostomised patients.	Same[1]
Patient Population	Adults with average height, weight, and anthropometrics	Adults with average height, weight, and anthropometrics	Same
Invasive or NonInvasive	Surgically Invasive	Surgically Invasive	Same
Maximum Use	Recommended 29 Days	Recommended 29 Days	Same
Functionality	Rota-Trach Tracheostomy Tube provides an alternate pathway for breathing when the natural airway is blocked or injured. It creates a direct route to the trachea, bypassing upper airway obstructions. It can be connected to respiratory equipment, like ventilators, to assist with breathing and provide mechanical ventilation.	Smiths Medical Portex® BLUselect® Tracheostomy Tube is intended for airway maintenance and is optionally available with a range of secondary features including cuff and fenestrations.	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 ISO 10993-1: 2009	Compatibility materials ISO 10993-1: 2009	Same
Biocompatibility evaluation endpoints	cytotoxicity, sensitization,	cytotoxicity, sensitization,	Similar[2]

Element of Comparison	**Proposed Device** Rota-Trach Disposable Standard Tracheostomy Tube	**Predicate Device:** K173384	**Comparison**
	irritation, acute systemic toxicity, pyrogenicity, subchronic toxicity, genotoxicity, implantation and chemical characterization.	irritation, acute systemic toxicity, pyrogenicity, subchronic toxicity, genotoxicity, and implantation.	
Shelf Life	3-year shelf life intended	5-year shelf life intended	Different [3]
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
Material Composition	Cannula: PVC; Cuff: PVC; Neck plate: PP; Pilot ballon w/t inflating tube: PVC; Introducer: HDPE; Neck strap: 100% Cotton. Disconnect wedge: PP	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	Plastic-based. Similar[4]
Performance testing per ISO 5366:2016	Yes	Yes	Same
Performance testing per ISO 5356-1	Yes	Yes	Same
Performance testing per ISO 18190	Yes	Yes	Same
Design Validation / Human Factors per ISO 62366	Yes	Yes	Same
Sterilization for ISO 11135, AAMI TIR28	Yes	Yes	Same

Note 1: The proposed device is only compared to “Smiths Medical Portex® BLUselect® Tracheostomy Tube”.
Note 2: Rota-Trach Disposable Standard Tracheostomy Tube completed the biocompatibility tests that included in predicate device. Rota-Trach Disposable Standard Tracheostomy Tube also conducted the testing of chemical characterization.
Note 3: The product stability tests of Rota-Trach Disposable Standard Tracheostomy Tube support 3-yest shelf life. It is different than the predicate device. It did not affect the decision of the substantial equivalent comparison.
Note 4: Both devices are plastic-based tubes. They both passed the relevant biocompatibility tests.

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J. SUMMARY OF PERFORMANCE DATA

The following performance data were provided to demonstrate the safety and efficacy:

Non-Clinical Testing Summaries

#	Test Standard	Result(s)
1.	ISO 5366:2016	PASS
2.	ISO 5356-1:2015	PASS
3.	ASTM F2250-903	PASS
4.	ISO 80369-7	PASS
5.	IEC 62366-1:2015	PASS
6.	ISO 11737-2:2009	PASS
7.	ISO 11607	PASS

Biocompatibility Assessment:

Rota-Trach Disposable Standard Tracheostomy Tube: externally communicating tissue/bone/dentin with breathing gas pathway contact more than 30 days.

This classification accounts for the cumulative use of a device intended to be replaced within 30 days by another of the same type.

The potential for adverse effects arising from exposure to a medical device is influenced by the intrinsic toxicity of the constituent materials, the processing methods applied during manufacturing, the route and level of patient exposure, and the intended clinical application.

A Table of Parts and Body Contact:

Part Name	Body Contact
Cannula	Tracheal mucosa
Cuff	Tracheal mucosa
Neck plate	Skin surface
15mm connector	No Contact
Pilot balloon w/t inflating tube	Tracheal mucosa
Introducer	Tracheal mucosa
Neck strap	Skin surface
Wedge	No Contact

To evaluate the biological safety of the Rota-Trach Disposable Standard Tracheostomy Tube, a comprehensive assessment was conducted. This included review of toxicological and biocompatibility data for device materials, analysis of the nature and duration of body contact, identification of potential risks associated with the manufacturing process and packaging, and consideration of patient exposure conditions.
To address any residual uncertainties and ensure compliance with ISO 10993 and relevant regulatory expectations, the following biological and chemical safety tests are proposed:

- In Vitro Cytotoxicity Test
- Skin Sensitization Study in Guinea Pigs
- Skin Irritation Study in White Rabbits
- Pyrogen Study in Rabbits
- Acute Systemic Toxicity Study
- Subacute Systemic Toxicity Study
- Subchronic Systemic Toxicity Study in Rats
- Genotoxicity Test
- Muscle Implantation Study in White Rabbits
- Chemical Characterization (per ISO 10993-18)
- Endotoxin Test (per USP <85>)
- Migration Test of Plasticizers
- Heavy Metal Analysis
- Residual Testing for Ethylene Oxide (EO), Ethylene Chlorohydrin (ECH), and Ethylene Glycol (EG)
- Test Report for Emissions of Particulate Matter
- Test Report for Emissions of Volatile Organic Compounds (VOCs) and Aldehydes
- Toxicological Risk Assessment Report for VOC Emissions

The materials used in the Rota-Trach Tracheostomy Tube have a well-documented history of safe use in medical and consumer products with similar contact profiles. Additionally, the manufacturing processes and packaging do not introduce any specific or novel safety risks.

Based on the data and test results provided, **Rota-Trach Disposable Standard Tracheostomy Tube** is not associated with toxicological risk, and the manufacturing process and packaging do not introduce additional safety concerns. No evidence suggests that the **Rota-Trach Disposable Standard Tracheostomy Tube** poses a biological risk. The proposed testing strategy ensures a robust assessment of the device's biocompatibility in line with current regulatory standards.

K.	SUBSTANTIAL EQUIVALENCE CONCLUSION	Based upon the information presented, **Vitaltec Corporation** concludes that the **Rota-Trach Disposable Standard Tracheostomy Tube** is substantially equivalent to predicate devices regarding indications for use, design, and testing results, without raising any safety and efficacy risks or concerns.