February 11, 2025

Teleflex Incorporated
Bouse Angela
Senior Manager Regulatory Affairs-Product Management
3015 Carrington Mills Blvd
Suite 600
Morrisville, North Carolina 27560

Re: K241451
Trade/Device Name: Rusch Endotracheal Tubes (Reinforced); Rusch Endotracheal Tubes (Safety Clear); Rusch Endotracheal Tubes (Safety Clear Pediatric)
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: May 22, 2024
Received: January 3, 2025

Dear Bouse Angela:

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
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241451

Device Name
Rusch Endotracheal Tubes (Reinforced);
Rusch Endotracheal Tubes (Safety Clear);
Rusch Endotracheal Tubes (Safety Clear Pediatric)

Indications for Use *(Describe)*
Reinforced Tube: Rusch Reinforced Endotracheal Tubes are designed for oral or nasal intubation and are indicated for airway management. The correct designation (oral, nasal or oral/nasal) is printed on the tube and unit package. Reinforced Endotracheal Tubes may be used to reduce the potential for kinking whenever an unusual positioning of the head or neck is required following intubation. The Reinforced Endotracheal Tubes are intended to be used on all patients requiring ventilation, pediatric and adult.

Safety Clear and Safety Clear Pediatric Tubes: Rusch Endotracheal Tubes, Cuffed and Uncuffed, with or without Murphy Eye are for oral or nasal intubation. They are indicated for airway management. The Rusch Endotracheal Tubes are intended to be used on all patients requiring ventilation, pediatric and adult.

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.

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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."

510(k) Summary

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Inc.
3015 Carrington Mill Blvd
Morrisville, NC 27560 USA
Phone: 919-332-8189

B. Contact Person

Angela Bouse
Principal Regulatory Affairs Specialist

C. Date Prepared

February 6, 2025

D. Device Name

Subject Device 1

Trade Name:	Rusch Endotracheal Tubes (Reinforced)
Common Name:	Tracheal Tube
Product Code:	BTR
Regulation Number:	21 CFR 868.5730
Classification Name:	Tube, Tracheal (W/Wo Connector)
Classification:	II
Classification Panel:	Anesthesia

Subject Device 2

Trade Name:	Rusch Endotracheal Tube (Safety Clear)
Common Name:	Tracheal Tube
Product Code:	BTR
Regulation Number:	21 CFR 868.5730
Classification Name:	Tube, Tracheal (W/Wo Connector)
Classification:	II
Classification Panel:	Anesthesia

Subject Device 3

Trade Name:	Rusch Endotracheal Tubes (Safety Clear Pediatric)
Common Name:	Tracheal Tube
Product Code:	BTR
Regulation Number:	21 CFR 868.5730
Classification Name:	Tube, Tracheal (W/Wo Connector)
Classification:	II
Classification Panel:	Anesthesia

E. Predicate Device
K990619 Rusch Reinforced Endotracheal (or Tracheal) Tube
K961837 Rusch Oral/Nasal Tracheal Tube/Safety Clear Plus Tracheal Tube
K993786 Rusch Oral/Nasal (Safety Clear Plus) Tracheal Tube

F. Device Description
An endotracheal tube is a device that is inserted into the trachea via the nose or the mouth to establish a patent airway to allow ventilation. The proposed Teleflex Medical Rusch Endotracheal Tubes are sterile, single use devices that are made non made with DEHP. The tracheal tubes contain a compatible cuff, inflation line, pilot balloon and one-way valve. A radiopaque line is incorporated into the full length of the Safety Clear tracheal tube, while the Reinforced tube contains an embedded stainless-steel spiral that allows for X-ray visualization. Each tracheal tube is supplied with an appropriately sized 15mm connector.

G. Indications for Use
See Substantial Equivalence Table Below

H. Contraindications
None

I. Substantial Equivalence
The subject devices are substantially equivalent to the predicate device with respect to intended use, technology, and construction. The differences between the predicate and the subject devices are minor and any risks have been mitigated through testing. The table below summarizes the differences between the subject and predicate device.

Substantial Equivalence Comparative Table: Reinforced Endotracheal Tube (Subject Device 1)

Features	Teleflex Medical Rusch Reinforced Endotracheal Tube (Subject Device 1)	Rusch/Teleflex Medical Reinforced Endotracheal Tube (Predicate K990619)	Comments
Classification Name	Tube, Tracheal (w/wo connector)	Same	Same
Product Code	BTR	Same	Same
Regulation Number	868.5730	Same	Same
Indications for Use	Rusch Reinforced Endotracheal Tubes are designed for oral or nasal intubation and are indicated for airway management. The correct designation (oral, nasal or oral/nasal) is printed on the tube and unit	Same	Same

	package. Reinforced Endotracheal Tubes may be used to reduce the potential for kinking whenever an unusual positioning of the head or neck is required following intubation. The Reinforced Endotracheal Tubes are intended to be used on all patients requiring ventilation, pediatric and adult.		
Environment of Use	Locations where ET intubation may be performed	Not stated	Same
Patient Population	Pediatric and Adult	Not stated	Same
Contraindications	None	Same	Same
Single Use	Yes	Same	Yes
Size Range	3.5 mm – 10.0 mm	2.5 mm – 11.0 mm	Within cleared range
Cuffed	Yes	Same	Same
Radiopaque	Yes	Same	Same
Connection to ventilation source	15 mm connector	Same	Same
Method of Sterilization	Ethylene Oxide 10-6 SAL	Same	Same
Biocompatibility	Materials have been tested per ISO 10993-1	Same	Same
Made without DEHP	Yes	No	While slightly different, the prosed device is made without the known hazardous substance
Sterile	Yes	Same	Same
Eye	Murphy	Same	Same
Graduations	Multiple cm markings	Same	Same
Shaft (main tube)	PVC	Same	Same
Cuff	PVC	Same	Same

Substantial Equivalence Comparative Table: Safety Clear Endotracheal Tube (Subject Device 2)

Features	Teleflex Medical Rusch Safety Clear Endotracheal Tube (Subject Device 2)	Rusch/Teleflex Medical Oral/Nasal Tracheal Tube/Safety Clear Plus Tracheal Tube (Predicate K961837)	Comments
Classification Name	Tube, Tracheal (w/wo connector)	Same	Same
Product Code	BTR	Same	Same
Regulation Number	868.5730	Same	Same
Indications for Use	Rusch Endotracheal Tubes, Cuffed and Uncuffed, with or without Murphy Eye are for oral or nasal intubation. They are indicated for airway management. The Rusch Endotracheal Tubes are intended to be used on all patients requiring ventilation, pediatric and adult.	Same	Same
Environment of Use	Locations where ET intubation may be performed	Not stated	Same
Patient Population	Pediatric and Adult	Not stated	Same
Contraindications	None	Same	Same
Single Use	Yes	Same	Yes
Size Range	4.5 mm – 10.00 mm	4.5 mm – 11.0 mm	Within cleared range
Cuffed	Yes	Same	Same
Radiopaque	Yes	Same	Same
Connection to ventilation source	15 mm connector	Same	Same
Method of Sterilization	Ethylene Oxide 10^{-6} SAL	Same	Same
Biocompatibility	Materials have been tested per ISO 10993-1	Same	Same
Made without DEHP	Yes	No	While slightly different, the

			prosed device is made without the known hazardous substance
Sterile	Yes	Same	Same
Eye	Murphy	Same	Same
Graduations	Multiple cm markings	Same	Same
Shaft (main tube)	PVC	Same	Same
Cuff	PVC	Same	Same

Substantial Equivalence Comparative Table: Safety Clear Pediatric Endotracheal Tube (Subject Device 3)

Features	Teleflex Medical Rusch Safety Clear Endotracheal Tube (Subject Device 2)	Rusch/Teleflex Medical Oral/Nasal Tracheal Tube/Safety Clear Plus Tracheal Tube (Predicate K961837)	Comments
Classification Name	Tube, Tracheal (w/wo connector)	Same	Same
Product Code	BTR	Same	Same
Regulation Number	868.5730	Same	Same
Indications for Use	Rusch Endotracheal Tubes, Cuffed and Uncuffed, with or without Murphy Eye are for oral or nasal intubation. They are indicated for airway management. The Rusch Endotracheal Tubes are intended to be used on pediatric.	Rusch Oral/Nasal Tracheal Tube, Cuffed, Magill/Murphy is a device inserted into a patient's trachea via the nose or mouth and used to maintain an open airway.	Similar, updated to align with the indication for the rest of the Rusch Safety Clear Endotracheal Tube product family.
Environment of Use	Locations where ET intubation may be performed	Not stated	Same
Patient Population	Pediatric	Not stated	Same
Contraindications	None	Same	Same
Single Use	Yes	Same	Yes
Size Range	2.5 mm – 4.0 mm	2.0 mm – 4.0 mm	Within cleared range
Cuffed	Yes	Same	Same

Radiopaque	Yes	Same	Same
Connection to ventilation source	15 mm connector	Same	Same
Method of Sterilization	Ethylene Oxide 10^{-6} SAL	Same	Same
Biocompatibility	Materials have been tested per ISO 10993-1	Same	Same
Made without DEHP	Yes	No	While slightly different, the prosed device is made without the known hazardous substance
Sterile	Yes	Same	Same
Eye	Murphy	Same	Same
Graduations	Multiple cm markings	Same	Same
Shaft (main tube)	PVC	Same	Same
Cuff	PVC	Same	Same

J. Comparison to the Predicate

The table above illustrates the similarities and differences between the subject and predicate devices. The basic technological and operating principles are the same for both devices. Although the indications for use wording is not identical, both the subject and predicate devices are for airway management. Both the subject and predicate devices are disposable, sterile, single patient use devices. The subject devices are substantially equivalent to the predicate device. There are no significant differences that would affect safety and efficacy.

K. Performance Data

The bench testing performed verifies that the performance of the subject device is substantially equivalent in terms of critical performance characteristics to the predicate device. These tests include:

- Testing performed included visual inspection, Dimensional testing, Bonding strength (main tube to the side arm, inflation tube and connector), Tube curvature, cuff restrained burst, Bevel angle Cuff inflation/deflation, Kink resistance, Cuff herniation, Cuff diameter, Tube collapse and Tracheal seal testing, as well as testing required by ISO 10993-1 Fifth Edition 2018-08 – Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing within a risk management process.

The testing performed verifies that the performance of the subject device is substantially equivalent in terms of critical performance characteristics to the predicate device.

Biological testing was performed according to ISO 10993:

- Cytotoxicity

- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Implantation
- Subacute Systemic Toxicity
- Genotoxicity
- Chemical Characterization-Exhaustive and Simulated Use. Toxicological Risk Assessment Related to Extractable and Leachables
- Particulates and VOC. Toxicological Risks Related to Inhalation of VOCs and Particulates

L. Conclusion

The subject device has the same intended use and technological characteristics and construction as the predicate. Test results demonstrate that the subject device meets it's intended use. It is for these reasons that the subject device can be found substantially equivalent to the predicate devices.