October 28, 2021

Teleflex Medical, Inc.
Lori Pfohl
Senior Regulatory Affairs Specialist
2917 Weck Drive
Research Triangle Park, North Carolina 27709

Re: K150603
Trade/Device Name: Rusch Safety Silk Pediatric Series Oral/Nasal Tracheal Tube
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal tube
Regulatory Class: Class II
Product Code: BTR

Dear Lori Pfohl:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on November 27, 2015. Specifically, FDA is updating this SE letter due to the clearance date not appearing on the original letter.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Todd Courtney, Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, 301-796-6371, todd.courtney@fda.hhs.gov.

Sincerely,

Todd D. Courtney -S

Todd Courtney
Assistant Director
DHT1C: Division of 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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Teleflex Medical, Inc.
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2917 Weck Drive
Research Triangle Park, NC 27709

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Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal tube
Regulatory Class: Class II
Product Code: BTR
Dated: November 5, 2015
Received: November 6, 2015

Dear Ms. Pfohl:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Erin I. Keith, M.S.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Rusch Safety Silk Pediatric Series Oral/Nasal Tracheal Tube

Indications for Use *(Describe)*

Rusch tracheal tubes are indicated for airway management by oral or nasal intubation of the trachea.

Intended Population: Pediatric

Intended Environment of Use: Locations where ET intubation may be performed

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

Rusch Safety Silk Pediatric Series Oral/Nasal Tracheal Tube

Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-491-8960
Fax: 919-433-4996

Contact Person

Lori Pfohl
Senior Regulatory Affairs Specialist

Date Prepared

3/9/2015

Device Name

Trade Name: **Rusch Safety Silk Pediatric Series Oral/Nasal Tracheal Tube**

Common Name: Tracheal Tube

Classification Name: Tube, Tracheal (Class II per 21 CFR 868.5730, Product Code BTR)

Predicate Devices

Teleflex Medical's Rusch Oral/Nasal (Safety Clear Plus) Tracheal Tube Cuffed, Magill/Murphy – K993786

Teleflex Medical's Rusch Oral/Nasal Tracheal Tube Cuffed, Magill/Murphy – K961837

Device Description

The proposed Teleflex Medical **Rusch Safety Silk Pediatric Tracheal Tube Series** tracheal tubes are sterile, single use devices that are made from Polyvinyl chloride (PVC) resin that is formulated without DEHP ("Non-DEHP" = < 0.1% DEHP w/w). 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 tracheal tube. Each tracheal tube is supplied with an appropriately sized 15mm connector.

The oral version of the device (Super Safety Silk) will be sold in both Murphy eye and Magill styles.

The nasal version of the device (Nasal Safety Silk) will be offered in the Murphy eye style only.

510(k) SUMMARY

Rusch Safety Silk Pediatric Series Oral/Nasal Tracheal Tube

Indications for Use

- Rusch tracheal tubes are indicated for airway management by oral or nasal intubation of the trachea.

Intended Population
- Pediatric patients

Intended Environment of Use
- Locations where ET intubation may be performed.

Contraindications

None

Substantial Equivalence

The proposed device is substantially equivalent to the predicate devices:

Features	Teleflex Medical Safety Silk Series Oral / Nasal Tracheal Tube (Proposed)	Teleflex Medical Oral / Nasal Tracheal Tube (Safety Clear Plus) (K993786)	Teleflex Medical Oral / Nasal Tracheal Tube (K961837)	Teleflex Medical Safety Silk Series Oral / Nasal Tracheal Tube (132415)
Classification Name	Tube, Tracheal (w/wo connector)	Same	Same	Same
Product Code	73 BTR	Same	Same	Same
Regulation Number	868.5730	Same	Same	Same
Indications for Use	Rusch tracheal tubes are indicated for airway management by oral or nasal intubation of the trachea..	Rusch Oral / Nasal Trachea 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.	Oral or nasal intubation and airway management	Same
Environment of Use	Locations where ET intubation may be performed	Not stated	Not stated	Same
Patient Population	Pediatric	Not stated	Not stated	Adult
Contraindications	None	Same	Same	Same
Single Use	Yes	Same	Same	Yes

510(k) SUMMARY

Rusch Safety Silk Pediatric Series Oral/Nasal Tracheal Tube

Features	Teleflex Medical Safety Silk Series Oral / Nasal Tracheal Tube (proposed)	Teleflex Medical Oral / Nasal Tracheal Tube (Safety Clear Plus) (K993786)	Teleflex Medical Oral / Nasal Tracheal Tube (K961837)	Teleflex Medical Safety Silk Series Oral / Nasal Tracheal Tube (Reference Predicate)
Size Range	3.0 mm – 4.5 mm	2.0 mm – 4.0 mm	4.5 mm – 11.0 mm	5.0 mm – 10.0 mm
Cuffed	Yes	Same	Same	Same
Radiopaque	Yes	Same	Same	Same
Connection to ventilation source	15 mm connector	Same	Same	Same
Method of Sterilization	Ethylene Oxide 10^{-6} SAL	Same	Same	Same
Biocompatibility	Materials have been tested per ISO 10993	Same	Same	Same
Made without DEHP	Yes	No	No	Yes
Packaging Configuration	Ten (10) individual units in a shelf box. Ten shelf boxes in a shipper	Not stated	Ten (10) individual units in a shelf box.	Same
Sterile	Yes	Same	Same	Same
Eye	Murphy and Magill	Same	Same	Same
Tip	Beveled	Same	Same	Same
Graduations	Multiple cm markings	Same	Same	Same
Shaft	PVC	Same	Same	Same
Cuff	PVC	Same	Same	Same
Pilot Balloon	PVC	Same	Same	Same
Inflation Valve	PVC	Same	Same	Same
Inflation Tube	PVC	Same	Same	Same
X-Ray Marker, Stripe	PVC with Barium Sulfate	Same	Same	Same
Connector	Polyamide	Polypropylene	Polypropylene	Same

Comparison to Predicate Device:

The proposed Safety Silk series tracheal tubes are substantially equivalent to the predicate devices with respect to indications for use, technology and construction. The differences between the predicate and the proposed devices are minor and any risks have been mitigated through testing. The proposed device is designed with essentially the similar materials as the predicate, and identical materials to the reference predicate

510(k) SUMMARY

Rusch Safety Silk Pediatric Series Oral/Nasal Tracheal Tube

- **Indications for Use –**
  The indications for use are substantially equivalent for the proposed device when compared to the predicates. Each device is indicated for Oral or Nasal use in airway management.

- **Technology and construction -**
  The design, fabrication, shape, size, etc. are substantially equivalent to the predicates. This design includes the disposable tracheal tube, cuff side arm assembly and 15mm connector.

- **Environment of use –**
  While not specifically stated, the environments of use are equivalent to predicates

- **Patient Population -**
  While not specifically stated, the patient population is equivalent to the predicate

- **Materials -**
  All patient contacting materials are in compliance with ISO 10993-1. Testing included Cytotoxicity, sensitization, intracutaneous activity, implantation and genotoxicity testing, and Extractables/Leachables Testing.

Performance Testing

Test	Reference to Standard (if applicable)	Principle of Test	Acceptance Criteria
Cuff Bonding Leak Evaluation	N/A	To perform a visual check at the welding point of the cuff	No leak around the welding area
Tube Curvature Test	ISO 5361	To measure the curvature of the tube	Must meet the product requirement of 140mm ± 20mm
Tube Collapse	ISO 5361	The patency of the ET tube airway lumen is tested by passing a steel ball through the tracheal tube lumen with the cuff inflated within a transparent tube	The steel ball (OD = 75% of the stated ID) must pass through the lumen freely.
Cuff Resting Diameter	ISO 5361	The resting diameter of the cuff is measured when the cuff is inflated to a reference pressure which is intended to remove creases but minimize stretching of its walls	The cuff resting diameter shall be within ± 15% of specification for each individual size
Cuff Herniation	ISO 5361	The tendency of the cuff to herniate beyond the plane perpendicular to the long axis of the tube at the nearest edge of the bevel is tested by applying an axial force with the cuff inflated within a transparent tube. A cuff which protrudes excessively at its patient end may partially or completely occlude the orifice at the patient end	No abnormality or defect on the cuff (any part of the inflated cuff reaches beyond the nearest edge of the bevel will be considered as defect). No abnormality on the configuration of the cuff during deflating the cuff over a period of not less than 10s (any abnormality will be considered as defect)."
Side Arm Bonding Strength	N/A	To evaluate the retention force of the inflation line connection to the Tracheal tube	Must be able to sustain a minimum of 15N
Connector Bonding Strength	N/A	The security of the attachment of the connector to the tracheal tube is tested by applying an axial separation force to the connector	Tube-Connector bonding must meet the minimum specification to 50N

510(k) SUMMARY

Rusch Safety Silk Pediatric Series Oral/Nasal Tracheal Tube

Test	Reference to Standard (if applicable)	Principle of Test	Acceptance Criteria
Tube Compression Evaluation	N/A	To measure the rigidity of the tube	Must be within the range of current data
Cuff Unrestrained Burst Evaluation	N/A	To determine minimum cuff burst pressure under unrestrained conditions	Must be within the range of current data
Cuff Restrained Burst Evaluation	N/A	To determine cuff burst volume under restrained conditions to simulate conditions in the trachea	Must be within the range of current data
Cuff Sealing Pressure Evaluation	N/A	To determine the minimum cuff pressure required to seal the corrugated tube	Must be within the range of current data

The **Rusch Safety Silk Pediatric Tracheal Tube Series** has the same indications for use, technological characteristics and construction as its predicates. Performance test results demonstrate that the proposed device meets its intended use. It is for these reasons that the proposed device can be found substantially equivalent.