510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
October 2, 2013

K133173

MAY 23 2014

Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-433-4908
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Contact Person

Lori Pfohl
Regulatory Affairs Specialist

Device Name

Trade Name: Rusch TracFlex Plus Pediatric Tracheostomy Tube Set

Common Name: Tracheostomy Tube

Classification Name: Tube Tracheostomy and tube cuff (Class II per 21 CFR 868.5800, Product Code JOH)

Predicate Devices

K023918 - Rusch Crystal Clear Tracheostomy Sets, Cuffed and Cuffless
K122235 - Rusch TracFlex Plus Tracheostomy Tube Set (Reference)

Device Description and Changes to Predicate

The **Rusch TracFlex Plus Pediatric Tracheostomy Tube Set** is a sterile, single patient use tracheotomy tube, available in sizes 3-6mm in 1 mm increments, with accessories which may be included in a set or sold separately. The device is used to provide an artificial airway. The device is introduced into a tracheotomy incision in the patient's neck that provides access to the trachea. The **TracFlex Plus Pediatric** tracheostomy tube is made from Polyvinyl chloride (PVC) resin that is formulated without DEHP ("Non-DEHP" = < 0.1% DEHP w/w), and is stainless steel spiral armored. It is available cuffed and uncuffed. Accessories included in the set are a disposable inner cannula, obturator, shower cap, cough cap and sealing cap. The tracheostomy tube is secured using the flange that is connected to the neck strap.

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The **Rusch TracFlex Plus Pediatric Tracheostomy Tube Set** is used in airway management of tracheostomized patients

Patient Population: Pediatric Patients

Environment of use: Home, Hospital and Sub-acute Institutions

Contraindications

Insurmountable intubation obstruction

For patients during radiation therapy and magnetic resonance imaging

Substantial Equivalence Comparison to Predicates

The proposed device is substantially equivalent to the predicate device:

Features	Proposed TracFlex Plus Pediatric	Predicate Crystal Clear K023918	Predicate (for reference) TracFlex Plus K122235
Device	Rusch TracFlex Plus Pediatric Tracheostomy Set	Rusch Crystal Clear Tracheostomy Sets, Cuffed and Cuffless	Rusch TracFlex Plus Tracheostomy Tube Set
Indications for use	The **Rusch TracFlex Plus Pediatric Tracheostomy Tube Set** is used in airway management of tracheostomized patients Patient Population: Pediatric Patients Environment of use: Home, Hospital and Sub-acute Institutions	The Rusch Crystal Clear Tracheostomy Sets, Cuffed and Cuffless are intended for airway management of tracheostomized patients.	The Rusch TracFlex Plus tracheostomy tube set is used in airway management of tracheostomized patients
Environment of Use	Home, Hospital and Sub-acute Institutions	Same	Same
Patient Population	Pediatric	Pediatric and adult	Adult
FDA Product Code	JOH 868.5800	Same	Same
Contraindications	Insurmountable intubation obstruction For patients during radiation therapy and magnetic resonance imaging	None	Same
Sizes	3-6	3.5 - 10.5 mm	7 to 11 mm
Fenestrated	No	Yes and No	No
Cuff (if present)	Low Pressure	Same	Same
Available in sets	Yes	Yes	Yes
Low pressure cuff	Spring return luer	same	Same

inflation system	operated valve		
Radiopaque	Yes	Yes	Yes
Stainless steel spiral reinforced tube	Yes	Yes	Yes
Method of Sterilization	Ethylene Oxide	Same	Same
Packaging Material	Thermoformed tray with Tyvek Lid	Same	Same
Inner cannula	Disposable	same	Same
Materials in patient contact	PVC and Silicone	same	Same
15 mm connector compliant to ISO 5356-1	Yes	Same	Same
Manufactured with DEHP (Non-DEHP)	No	Yes	No

- **Indications for Use** – The indications for use are identical for the proposed device when compared to the predicate – K023918. Each device is indicated for use in airway management of tracheostomized patients.

- **Technology and construction** - The design, fabrication, shape, size, etc. are equivalent to the predicate – K023918. This design includes the disposable inner cannula, obturator, shower cap, cough cap and sealing cap. They are available in sizes from 3.0 to 6.0mm OD.

- **Environment of use** – The environments of use are identical to predicate – K023918

- **Patient Population** -The patient population is identical to the predicate – K023918

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

Comparison to Predicate Device:

The proposed **TracFlex Plus Pediatric** tracheostomy 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 different materials than the main predicate, but essentially identical materials to the reference predicate. The proposed device is Non-DEHP.

Non-clinical Comparative Performance Testing

A brief summary of tests relied upon to demonstrate substantial equivalence to the predicate can be found in the table below:

Test	Reference to Standard (if applicable)	Principle of Test
Connector bonding strength	ISO 5366-3	The security of the attachment of the connector to the tracheostomy tube is tested by applying an axial separation force to the connector
Flange (neck-plate) bonding strength	ISO 5366-3	The security of the attachment of the neck-plate to the tracheostomy tube is tested by applying an axial separation force to the neck-plate (flange)
Cuff resting diameter	ISO 5366-3	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
Tube collapse	ISO 5366	The patency of the tracheostomy tube airway lumen is tested by passing a steel ball through the tracheostomy tube lumen with the cuff inflated within a transparent tube
Cuff herniation	ISO 5366	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
Cuff Burst Evaluation	N/A	The cuff restrained burst test is designed to ensure the cuff will not burst or rupture when inflated inside the trachea
Cuff Bond Strength	N/A	To evaluate the strength needed to separate the cuff from the tube
Side arm bonding strength	N/A	To evaluate the retention force of the inflation line connection to the Tracheostomy tube
Ink adhesion test	N/A	To ensure the printing remains legible after the aging and sterilization processes and being wiped with a solvent

Substantial Equivalence Conclusion

The **Rusch TracFlex Plus Pediatric** has the same indications for use, patient population and technology of construction as the predicate device. Performance test results demonstrate that the proposed device meets its intended use. It is for these reasons that the the devices can be found substantially equivalent.

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

May 23, 2014

Teleflex Medical, Incorporated
Lori Pfohl
Senior Regulatory Affairs Specialist
2917 Week Drive
Research Triangle Park, NC 27709

Re: K133173
Trade/Device Name: Rusch TracFlex Plus Pediatric Tracheostomy Tube Set
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy tube and tube cuff.
Regulatory Class: Class II
Product Code: JOH
Dated: April 24, 2014
Received: April 25, 2014

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.

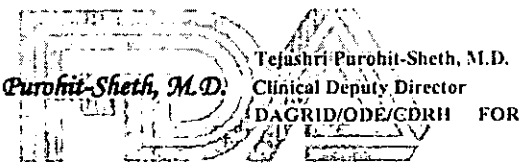
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



Tejashri Purohit-Sheth, M.D.

Erin I. Keith, M.S.
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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)*
K133173

Device Name
Rusch TracFlex Plus Pediatric Tracheostomy Tube Set

Indications for Use *(Describe)*

The Rusch TracFlex Plus Pediatric Tracheostomy Tube Set is used in airway management of tracheostomized patients.

Patient Population: Pediatric Patients per below:

Pediatric Subgroup	Approximate Age Range
Neonate/Newborn	Birth to 28 days
Infant	29 days to < 2 years
Child	2 years to <12 years
Adolescent	12 years to <18 years
Transitional Adolescent A	18 years to <21 years

Environment of use: Home, Hospital and Sub-acute Institutions

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)*

FDA

Anya C. Harry -S
2014.05.23
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