K122235

510(k) SUMMARY
August 6, 2013

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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SEP 06 2013

Contact Person

Lori Pfohl
Regulatory Affairs Specialist

Device Name

Trade Name: Rusch TracFlex Plus 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 Device

Rusch Ultra TracheoFlex Teleflex Medical, Inc - K964056

Device Description and Changes to Predicate

The **Rusch TracFlex Plus Tracheostomy Tube Set** is a sterile, single patient use tracheotomy tube, available in sizes 7-11mm 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, in order to provide access to the patient's airway. The device is introduced into a tracheotomy incision in the patient's neck that provides access to the trachea. The **TracFlex Plus** 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.

Indications for Use

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

- This device is intended for use on adult patients

Intended Environment of Use –

- This device is intended for use in hospital and hospital-type facilities, surgery centers and home care environments.

The product is single patient, multi-use

Contraindications

Use of the Rusch TracFlex Plus is contraindicated in patients having abnormal upper airway or pathology and 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)	Predicate (Ultra Tracheoflex) K964056
Device	Rusch TracFlex Plus Tracheostomy Tube Set	Rusch Ultra Tracheoflex Tracheostomy Kits K964056
Indications for use	The Rusch TracFlex Plus tracheostomy tube set is used in airway management of tracheostomized patients	Tracheostomy tube kits intended for airway management in a tracheostomized patient
FDA Product Code	JOH 868.5800	Same
Environment of Use	Home, Hospital, Sub-acute Institutions	Same
Patient Population	Adult	Same
Contraindications	Use of the TrachFlex Plus Tracheostomy Set is contraindicated in patients having abnormal upper airway anatomy or pathology For patients during radiation therapy and magnetic resonance imaging	Use of the Rusch Ultra Tracheoflex Tracheostomy Set is contraindicated in patients having abnormal upper airway anatomy or pathology
Sizes	7 to 11 mm	6-11 mm
Fenestrated	No	Yes and No
Cuff (if present)	Low Pressure	Same
Available in sets	Yes	Yes
Pilot balloon (cuffed version)	Pressure indicating	same
Flange	Adjustable	Fixed
Low pressure cuff inflation system	Spring return luer operated valve	same
Radiopaque	Yes	Yes
Stainless steel spiral reinforced tube	Yes	Yes
Method of Sterilization	Ethylene Oxide	Same
Packaging Material	Thermoformed tray with Tyvek Lid	Same

Features	Proposed (TracFlex Plus)	Predicate (Ultra Tracheoflex) K964056
Inner cannula	Disposable	same
Tube Components	15 mm connector Flange Neck Plate Introducer / obturator Cuffed/Uncuffed Pilot balloon	Same
Accessories	yes	yes
15 mm connector compliant to ISO 5356-1	yes	yes

- **Indications for Use** – The indications for use are identical for the proposed device when compared to the predicate – K964056. 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 – K964056. This design includes the disposable inner cannula, obturator, shower cap, cough cap and sealing cap. They are available in sizes from 7.0 to 11.0 mm OD.

- **Environment of use** – The environments of use are identical to predicate – K964056

- **Patient Population** -The patient population is equivalent to the predicate – K964056

- **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 essence of this change is to add a Non-DEHP PVC version of the previously cleared PVC tracheostomy tube. This change also changes the inner cannula material from polyurethane to polyethylene. The proposed device is substantially equivalent in intended use, design, performance and principles of operation to the identified predicate devices cleared under K964056. The differences between the Rusch TracFlex Plus and the predicate device are minor and raise no new issues of safety and efficacy.

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 5366-1 Section 6.1 Machine end	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 5366-1 Section 6.2. Neck-plate	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 5366-1 Section 6.4.3	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 5361 section 4.5 for cuff tests	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
Cuff herniation	ISO 5361 section 4.5 for cuff tests	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	N/A	To ensure the printing remains legible after the aging and sterilization processes and being wiped with a solvent
DEHP testing	ISO 10993-17 and 10993-18	Extractions are performed to determine the content of DEHP in the total device
Dimensional evaluation (Inner cannula)	N/A	To verify the inner cannula component meets the engineering drawing
Dimensional evaluation (Silicone stopper ring)	N/A	To verify the silicone stopper ring component meets the engineering drawing
Inner Cannula tensile strength after silicone coating	N/A	To determine the tensile strength of the inner cannula after the coating process
Ink Adhesion Test	N/A	To ensure the ink adheres to the inner cannula surface
Assembly Bonding Strength	N/A	To determine the bond strength between the stopper and the inner cannula
Kinking Test	N/A	To ensure the patency of the inner cannula during use
Biocompatibility	ISO 10993-1	To demonstrate biocompatibility of the materials used. Testing included cytotoxicity, sensitization, intracutaneous activity, genotoxicity and implantation testing

Substantial Equivalence Conclusion

The **Rusch TracFlex Plus** has the same indications for use, technological characteristics and construction as its predicate. Performance test results demonstrate that the proposed device is substantially equivalent and because pass/fail criteria has been met, 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

September 6, 2013

Teleflex Medical, Incorporated
Ms. Lori Pfohl
Regulatory Affairs Specialist
2917 Weck Drive
RESEARCH TRIANGLE PARK NC 27709

Re: K122235
Trade/Device Name: Rusch TracFlex Plus Tracheostomy Tube Set
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: JOH
Dated: August 7, 2013
Received: August 8, 2013

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.

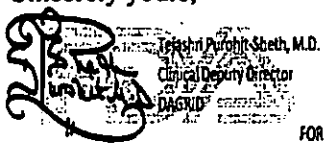
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K122235

Device Name: Rusch TracFlex Plus Tracheostomy Tube Set

Indications for Use:

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

Prescription Use XX
(Part 21 CFR 801 Subpart D)

Over-the-counter use __
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Tejashri S. Purohitsheth -S
Clinical Deputy Director,
DAGRID
2013.09.06 15:44:03 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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