

510(k) SUMMARY
February 14, 2013

Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
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NOV 06 2013

Contact Person

Lori Pfohl
Regulatory Affairs Specialist

Device Name

Trade Name: **Rusch EasyCric Emergency Cricothyrotomy Set**

Common Name: Emergency Cricothyrotomy Kit

Classification Name: Emergency Airway Needle (Class II per 21 CFR 868.5090,
Product Code BWC, Class 2)

Predicate Device

Melker Emergency Cricothyrotomy Catheter Set - K013916

Device Description

The **Rusch EasyCric Emergency Cricothyrotomy Set** is a sterile, single use emergency cricothyroidotomy set available in size 5 mm. The device employs the Seldinger technique to provide an emergency artificial airway when attempts to intubate the trachea fail. Cricothyroidotomy provides faster access in emergency situations than surgical or percutaneous tracheostomy, which are time consuming procedures. The device gains access by cutting the link between the cricoid cartilage and the thyroid cartilage into the ligamentum conicum. It is available uncuffed. Components of the set include the EasyCric tube and insertion dilator, scalpel, puncture needle, syringe, guidewire, comfort neckband and saline solution.

Indications for Use

Rusch EasyCric Emergency Cricothyrotomy Set is indicated to provide emergency airway access when conventional ventilation by intubation or face mask cannot be performed.

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Patient Population: Adult Patients

Environment of Use: Hospital Operating Room, Intensive Care Unit, the Emergency Room or out of the Hospital

Substantial Equivalence

The proposed device is substantially equivalent to the predicate device:

Features	Proposed	Predicate K013916
Device	Rusch EasyCric Emergency Cricothyrotomy Set	Melker Emergency Cricothyrotomy Catheter Set
Indications for use	Rusch EasyCric Emergency Cricothyrotomy Set is indicated to provide emergency airway access when conventional intubation cannot be performed	Melker Emergency Cricothyrotomy Catheter Set is used for emergency airway access in patients whom conventional endotracheal intubation and ventilation cannot be performed
FDA Product Code	BWC 868.5090	BWC 868.5090 JOH 868.5800
Class	II	II
Environment of Use	Hospital Operating Room, Intensive Care Unit, the Emergency Room or out of the Hospital	Not Stated
Patient Population	Adult	Same
Contraindications	None	None
Technology applied	Seldinger Technique via the cricothyroid membrane	Same
Single use	Yes	Same
Size (Main Tube) ID	5 mm	3.5mm, 4.0mm and 6.0mm
Main Tube length	7cm	3.8cm, 4.2cm, and 7.5cm
Cuff	No	Same
Available in sets	Yes	Same
Connection to ventilation source	15 mm connector	Same
Method of Sterilization	Ethylene Oxide 10 ⁻⁶ SAL	Same
Basic Materials of construction	Polypropylene Polyethylene Nylon PVC ABS Nickel Stainless steel	PVC Remainder Unknown

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Features	Proposed	Predicate K013916
Set Components	Main tube Curved dilator Guidewire with flexible tip Scalpel Metal Needle Comfort Neckband Syringe Saline Pouch	Main tube Curved dilator Guidewire with flexible tip Scalpel TFE Catheter needle, Entry needle Syringe Trach tape
Performance testing	<ul style="list-style-type: none"> • Connector bonding strength • Flange (neck-plate) bonding strength • Connector Fit Test (ring gauge test) • Coating consistency on the tube • Coating lubricity • Visual Inspection of Saline, Scalpel and Neckband • Guidewire testing 	Not Stated

- **Indications for Use** – The indications for use are identical for the proposed device when compared to the predicate – K013916. Each device is indicated for use in emergency airway management when conventional intubation cannot be performed.
- **Technology and construction** - The design, fabrication, shape, size, etc. are equivalent to the predicate – K013916. Both the proposed and predicate devices use the Seldinger technique to gain access to the airway.
- **Environment of use** – The environments of use are equivalent to predicate – K013916
- **Patient Population** -The patient population is equivalent to the predicate – K013916
- **Materials** -All patient contacting materials are in compliance with ISO 10993-1. Testing performed is listed in the performance summary table below.

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Performance – 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	Acceptance Criteria
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	Must be able to sustain axial force of $15 \pm 1.5N$ without movement
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)	Must be able to sustain axial force of $15 \pm 1.5N$ without movement
Connector Fit Test (ring gauge test)	ISO 5356: Section 5.1	To ensure the connector is compatible with other supporting connectors and devices	The connector's leading edge shall lie between the minimum and maximum diameter steps of the gauge.
Coating consistency on the tube	N/A	Determines coating consistency	Smooth and even coating on the tube
Coating lubricity	N/A	Determines coating lubricity	Wear value of less than 150%
Visual Inspection of Saline, Scalpel and Neckband	N/A	Demonstrates these components remain intact	No torn packaging or damage to the product
Guidewire testing	N/A	Demonstrates guidewire remains compatible with the introducer and needle post worst case conditions	Smooth insertion without restriction
Biocompatibility testing	10993-1	Testing was performed based on mucosal/external communicating contact of limited duration (<24 hrs.). Hemolysis testing was also performed due to possible tissue contact.	Must meet the requirements as outlined in ISO 10993-1

The **Rusch EasyCric** has the same indications for use, technological characteristics and construction as its predicate. Performance test results demonstrate that the proposed device does not raise new questions of safety and effectiveness and because pass/fail criteria has been met, the devices can be found substantially equivalent.



November 6, 2013

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

Re: K130405

Trade/Device Name: Rusch EasyCric Emergency Cricothyrotomy Set
Regulation Number: 21 CFR 868.5090
Regulation Name: Emergency Airway Needle
Regulatory Class: Class II
Product Code: BWC
Dated: October 4, 2013
Received: October 7, 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,

Mary S. Runner -S

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: K130405

Device Name: **Rusch EasyCric Emergency Cricothyrotomy Set**

Indications for Use:

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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)

Anya C. Harry
-S

FDIA
Digitally signed by Anya C. Harry -S
DN: cn=U.S. Government, ou=HHS,
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serial=421220300.1.1=0011315590
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