K043205

Teleflex MEDICAL

JAN - 7 2005

Teleflex Medical Group Headquarters
2345 Waukegan Road
Bannockburn, IL 60015 USA
Phone: 847-572-8002
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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Rüsch Easy Tube

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

Teleflex Medical Group Headquarters
2345 Waukegan Road
Bannockburn, IL 60015 USA
Phone: 847-572-8002
Fax: 847-572-8001

B. Contact Person

Lori Hays
Senior Manager, Regulatory Affairs

C. Date Prepared

November 18, 2004

D. Device Name

Trade Name: Rüsch Easy Tube

Common Name: Tracheal Tube

Classification Name: Tube, Tracheal (w/wo Connector)

Product Code: BTR

Regulation Number: 868.5730

Class: II

E. Device Description

The Rüsch Easy Tube consists of a 28 Fr (Small) or 41 Fr (Large), clear, twin lumen tube with a radiopaque stripe and graduated centimeter markings. The 28 Fr size is for use with patients 90 – 130 cm in height. The 41 Fr size is for use with patients over 130 cm in height.

The device is designed to occlude the oro- and nasopharynx. The tube has a PVC high volume, low pressure, inflatable distal esophageal cuff and a larger proximal oropharyngeal cuff. Both cuffs are provided with self-sealing luer connector valves. A color-coded pilot balloon is provided for each of the cuffs. The color coding facilitates identification of the cuff/pilot balloon relationship. The clear pilot balloon corresponds with the clear distal cuff. The blue pilot balloon corresponds with the green proximal cuff. The shaft for the proximal cuff is also color-coded with a matching blue sleeve.

F. Intended Use

The Rüsch Easy Tube is a sterile single patient use, combination esophageal/tracheal tube intended to be used for emergency intubation, difficult intubation or general anesthesia intubation. The device will provide sufficient ventilation whether the airway is placed into the esophagus or into the trachea.

G. Substantial Equivalence

The Rüsch Easy Tube is substantially equivalent to the Kendall Combitube (K844746) in intended use, design and components, materials, and performance characteristics. See Table 1.

Table 1

Comparison Point	**Easy Tube**	**Kendall Combitube – K844746**
Intended Use	To be used for emergency, difficult or general anesthesia intubation. The device will provide sufficient ventilation whether the airway is placed into the esophagus or into the trachea.	To be used for emergency, difficult or general anesthesia intubation. The device will provide sufficient ventilation whether the airway is placed into the esophagus or into the trachea.
I.D. Size	Small - 28Fr Large - 41Fr	Small Adult - 37Fr, Regular - 41Fr
Cuff Style	High Volume, Low Pressure	High Volume, Low Pressure
Pilot Balloons – Color Coded	Yes	Yes
Tube Available Separately	Yes	Yes
Graduations	Yes	No
Radiopaque Marker	Yes	No
Inflation Valve Type	Luer Activated	Luer Activated
Sterile	Yes	No

H. Summary of Testing

All materials used in the fabrication of the Rüsch Easy Tube were evaluated through biological qualification safety tests as outlined in ISO 10993 Part 1 "Biological Evaluation of Medical Devices". Comparative testing was performed. The materials used were also tested in accordance with industry recognized test methods and were found to be acceptable for the intended use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Lori Hays
Senior Manager, Regulatory Affairs
Teleflex Medical Group Headquarters
2345 Waukegan Road
Bannockburn, Illinois 60015

Re: K043205
Trade/Device Name: Rüsch Easy Tube
Regulation Number: 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: November 18, 2004
Received: November 19, 2004

Dear Ms. Hays:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Julie Michaud MD for DR. CHIU LIN

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name: Rüsch Easy Tube

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The Rüsch Easy Tube is a sterile, single use, combination esophageal/ tracheal tube intende to be used for emergency intubation, difficult intubation or general anesthesia intubation. Th device will provide sufficient ventilation whether the airway is placed into the esophagus or in the trachea

Michael D MD
FOR DR. CHIU LIN

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

510(k) Number: K043205

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)