JUL 2 3 2002

K021764

RÜSCH
INTERNATIONAL
Group Regulatory Affairs
A Subsidiary of Teleflex Incorporated (USA)

Tall Pines Park
Jaffrey, NH 03452
(603) 532-7706
FAX (603) 532-8211 or 6108

510(k) Summary

1. Submitter Name, Address, and Date of Submission:

Rick Lykins
Group RA Manager - US
Rüsch International
Tall Pines Park
Jaffrey, NH 03452
Telephone Number: (603) 532-0204
Fax Number: (603) 532-6179

E-Mail: rlykins@tfx.com

Contact: Same as above

2. Name of the Device, Common, Proprietary (if known), and Classification:

Classification Name: Tube, Tracheostomy (W/WO Connector)

Common Name: Tracheostomy Tube

Proprietary Name: Rüsch TracheoFix Set, Cuffed
Rüsch TracheoFix Set, Uncuffed

3. Identification of the legally marketed device to which the submitter claims equivalence:

The Rüsch TracheoFix Set is substantially equivalent in design and materials to:

- The Mallinckrodt Shiley DCT Tracheostomy Tube Cuffed and Uncuffed
- The Smiths Industries (SIMS Concord-Portex) D.I.C. (**D**isposable **I**nner **C**annula) Tracheostomy Tubes, Cuffed and Uncuffed
- The Bivona Medical Technologies AIRE-CUF© Tracheostomy Tube (Predicate to Rüsch cuffed version only)
- Rüsch Crystal Tracheostomy Tube (Predicate to Rüsch cuffed version only)

- Rüsch TracheoFlex Sets (Predicate to Rüsch cuffed version only)

4. Description of the Device:

TracheoFix Sets will be offered in two (2) versions – Cuffed and Uncuffed. Descriptions are as follows:

Rüsch TracheoFix Set, Cuffed:

The Rüsch TracheoFix Set, Cuffed consists of a polyvinylchloride (PVC) outer tube with low pressure cuff and pilot balloon, a PVC flexible flange with a PVC turn lock fastener. The flange on this device is not adjustable. In addition, the set will also include a polyethylene cannula with standard taper and a replacement cannula which will be offered separately as an accessory, a polyethylene introducer, a standard nylon connector, a Velcro head band also offered separately as an accessory, an ABS phonation valve, an ABS cough cap and an ABS sealing cap.

This set will be offered in a variety of sizes from 7.0mm, to 11.0mm in 0.5mm increments. The size determinations are the Inside Diameter (I.D.) of the outer tube.

Rüsch TracheoFix Set, Uncuffed:

The Rüsch TracheoFix Set, Uncuffed consists of a polyvinylchloride (PVC) outer tube, a PVC flexible flange with a PVC turn lock fastener. The flange on this device is not adjustable. In addition, the set will also include a polyethylene inner tube with standard taper and a replacement inner tube which will be offered separately as an accessory, a polyethylene introducer, a standard nylon connector, a Velcro head band which will also be offered as an accessory, an ABS phonation valve, an ABS cough cap and an ABS sealing cap.

This set will be offered in a variety of sizes from 7.0mm, to 11.0mm in 0.5mm increments. The size determinations are the Inside Diameter (I.D.) of the outer tube.

Each Rüsch TracheoFix Set, Cuffed and Uncuffed will be provided sterile, by either Gamma Irradiation or Ethylene Oxide, in a clear plastic thermoformed tray with a Tyvek barrier/label. Each pack will be individually labeled. The device will then be packaged in a labeled outer cardboard carton. The device will be marketed one unit per box. The Velcro headband and the inner cannula will be marketed separately as accessories under separate part numbers. Both accessories will be marketed sterile, individually packaged and labeled, ten (10) units per box.

5. Intended Use of the Device:

The Rüsch TracheoFix Set (TFS) is a single patient disposable tracheostomy tube for airway management of tracheostomized patients.

6. Summary of Technological Characteristics:

The Rüsch TracheoFix Set is identical in materials to the 510(k) # K972423, Rüsch TracheoFix Set, which was determined to be substantially equivalent on February 13, 1997. An uncuffed version has been added to this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2002

Mr. Rick Lykins
Group RA Manager
Rusch International
Tall Pines Park
Jaffrey, New Hampshire 03452

Re: K021764
Trade/Device Name: Rusch TracheoFix Set
Regulation Number: 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: BTO
Dated: May 28, 2002
Received: May 29, 2002

Dear Mr. Lykins:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021764

Device Name: Rüsch TracheoFix Set

Indications for Use:

The Rüsch TracheoFix Set (TFS) is a single patient disposable tracheostomy tube for airway management of tracheostomized patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021764