MAR 2 8 2003

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

K023918

## 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 Crystal Clear Tracheostomy Set, Cuffed<br>Rüsch Crystal Clear Tracheostomy Set, Cuffless |

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

The Rüsch Crystal Clear Tracheostomy Sets are substantially equivalent in design and materials to:

Rüsch Crystal Tracheostomy Set - K972546

## 4. Description of the Device:

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

The Rüsch Crystal Clear Tracheostomy Sets will be offered in two (2) versions - Cuffed and Cuffless. Descriptions are:

***Rüsch Crystal Clear Tracheostomy Set, Cuffed:***

The Rüsch Crystal Clear Tracheostomy Set, Cuffed consists of a polyvinylchloride (PVC) tracheostomy tube with high volume/low pressure cuff, pilot balloon and tapered tip to facilitate insertion, a PVC flexible neck plate with a Nylon 15mm swivel connector and a polyethylene obturator with a tapered tip to facilitate insertion. The flange on this device is not adjustable. In addition, a PVC disposable inner cannula will be offered separately as an accessory.

This set will be offered in a range of sizes from 3.5mm - 10.5mm in 0.5mm increments. The size determinations are the Inside Diameter (I.D.) of the tracheostomy tube.

***Rüsch Crystal Clear Tracheostomy Set, Cuffless:***

The Rüsch Crystal Clear Tracheostomy Set, Cuffless consists of a polyvinylchloride (PVC) tracheostomy tube with a tapered tip to facilitate insertion, a PVC flexible flange with a PVC turn lock fastener neck plate with a Nylon 15mm swivel connector and a polyethylene obturator with a tapered tip to facilitate insertion. The flange on this device is not adjustable. In addition, a PVC disposable inner cannula will be offered separately as an accessory.

This set will be offered in a range of sizes from 3.5mm - 10.5mm in 0.5mm increments. The size determinations are the Inside Diameter (I.D.) of the tracheostomy tube.

Each Rüsch Crystal Clear Tracheostomy Set, Cuffed and Cuffless will be provided sterile, by either Gamma Irradiation or Ethylene Oxide, inside a protective inner pouch in a blister pack sheet with a Tyvek paper seal to provide a sterility barrier. Each pack will be individually labeled. The device will then be packaged, five units per carton, in a labeled outer cardboard carton. The inner cannulae will be marketed separately as accessories under separate part numbers.

**5. Intended Use of the Device:**

The Rüsch Crystal Clear Tracheostomy Sets, Cuffed and Cuffless are intended for airway management of tracheostomized patients.

**6. Summary of Technological Characteristics:**

The Rüsch Crystal Clear Tracheostomy Sets are identical in materials and sizes to the 510(k) # K972546, Rüsch Crystal Tracheostomy Set, which was determined to be substantially equivalent on April 14, 1998. The 3.0mm and 11.0mm sizes indicated in K972546 have been removed from the current product line.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2003

Mr. Rick Lykins
Group RA Manager
Rüsch International
50 Plantation Drive
Jaffrey, New Hampshire 03452

Re: K023918
Trade/Device Name: Rusch Crystal Clear Tracheostomy Sets, Cuffed and Cuffless
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: 73 JOH
Dated: November 21, 2002
Received: November 25, 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), 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,

Susan Runner

Susan Runner, DDS, MA
Interim 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):** K023918

**Device Name:** Rüsch Crystal Clear Tracheostomy Sets, Cuffed and Cuffless

**Indications for Use:**

The Rüsch Crystal Clear Tracheostomy Sets, Cuffed and Cuffless are intended 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)

Susan Runyon

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

510(k) Number: K023918