K972423

FEB 13 1998

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

[As required by 21 CFR 807.92]

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

Mr. James R. Whitney
Group Regulatory Affairs Associate
Willy Rüsch AG Group
Tall Pines Park
Jaffrey, New Hampshire 03452

Telephone: (603) 532-7706

Contact: Same as above

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

Classification Name: Tracheostomy Tube

Common Name: Tracheostomy Tube

Proprietary Name: TracheoFix-Set

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

The Rüsch TracheoFix-Set is substantially equivalent in design, use, and materials to the Mallinckrodt (Shiley) Disposable Cannula Low Pressure Cuffed Tracheostomy Tube, the Smiths Industries Medical Systems (Concord/Portex) D.I.C. Tracheostomy Tubes, Cuffed and the Bivona Medical Technologies AIRE-CUF® Tracheostomy Tube.

4. Description of the Product:

The TracheoFix-Set consists of the following:

- outer tube with low pressure cuff and pilot balloon, flexible fixation flange and turn lock fastener (the flange is not adjustable).

- luer activated valve for cuff inflation/deflation
- inner tube with standard taper and a replacement inner tube
- introducer
- standard connector
- neck band

The Rüsch TracheoFix-Set is a sterile, single patient, reusable, cuffed, low pressure tracheostomy tube.

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 following technological characteristics are the same as or equivalent to predicate devices:

The TracheoFix-Set Cuffed tracheostomy tube is equivalent to predicate devices in materials, design characteristics, function and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. James R. Whitney
Group Regulatory Affairs Associate
Rüsch International
Tall Pines Park
Jaffrey, NH 03452

Re: K972423
Rüsch TracheoFix-Set
Regulatory Class: II (two)
Product Code: 73 JOH
Dated: November 14, 1997
Received: November 17, 1997

Dear Mr. Whitney:

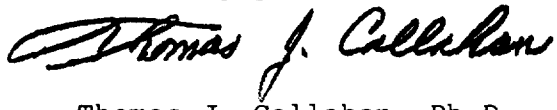
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: 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)

[redacted]

(Division Sign-Off)
Division of Cardiovascular, [redacted]
and Neurological Devices
510(k) Number K972423

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)