K023964

DEC 2 3 2002

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, Tracheal w/wo Connector

Common Name: Tracheal Tube

Proprietary Name: Rüsch Microlaryngeal Tube

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

The Rüsch Microlaryngeal Tube is substantially equivalent in design and materials to:

Rüsch Safety Tracheal Tubes - Preamendment
Rüsch AGT PVC Preformed Nasal Tracheal Tubes - K931163/K931166
Rüsch Oral/Nasal (Safety Clear Plus™) Tracheal Tube, Cuffed, Magill/Murphy, Sterile - K993786
Rüsch Edgar Tube - K021540
Sheridan® (Now Hudson RCI) LTS™ Tracheal Tube for Microlaryngeal Tracheal Surgery - K860176
Mallinckrodt (Now Nellcor) MLT® Microlaryngeal Tracheal Tube - K801005

4. Description of the Device:

The Rüsch Microlaryngeal Tube will be offered in three (3) sizes - 4.0mm, 5.0mm and 6.0mm ID. The devices will have a low-pressure/high volume cuff, inflated via a luer activated valve. A pilot balloon will be provided to give a visual indication of cuff status.

The Rüsch Microlaryngeal Tube consists of a clear, implant-tested tracheal tube with a radiopaque stripe. The main tube is graduated with multiple centimeter markings to facilitate determination of intubated length.

5. Intended Use of the Device:

The Rüsch Microlaryngeal Tube is a sterile, single-use, oral/nasal tracheal tube intended to be used for airway management during laryngeal procedures.

6. Summary of Technological Characteristics:

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

Materials:

The Rüsch Microlaryngeal Tube is manufactured from the same material (trade name Rüschelit) and manufactured by the same processes as the Rüsch Safety Tracheal Tubes which were in interstate commerce prior to May 28, 1976, the Rüsch AGT Preformed Nasal Tracheal Tubes, K931163 and K931166 which were determined to be substantially equivalent by the Agency June 23, 1993 and June 22, 1993 respectively, the Rüsch Oral/Nasal (Safety Clear Plus™) Tracheal Tube, Cuffed, Magill/Murphy, Sterile, K993786 which was determined to be substantially equivalent by the Agency February 2, 2000 and, most recently, the Rüsch Edgar Tube, K021540 which was determined to be substantially equivalent by the Agency August 1, 2002.

Size Range:

The Rüsch Microlaryngeal Tube will be offered in three (3) sizes - 4.0mm, 5.0mm and 6.0mm ID. Both the Mallinckrodt MLT® Microlaryngeal Tracheal Tube - K801005 and the Sheridan® LTS™ Tracheal Tube for Microlaryngeal Tracheal Surgery - K860176 are marketed in identical sizes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2002

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

Re: K023964
Trade/Device Name: Rusch Microlaryngeal Tube
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: 73 BTR
Dated: November 26, 2002
Received: November 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), 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,

Robert Betz DVS for T. A. Ulatowski

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): K 023964

Device Name: Rüsch Microlaryngeal Tube

Indications for Use:

The Rüsch Microlaryngeal Tube is a sterile, single-use, oral/nasal tracheal tube intended to be used for airway management during laryngeal procedures.

(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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K023964