K021540

AUG 01 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: Endotracheal or Tracheal Tube

Proprietary Name: Rüsch EDGAR Tube

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

The Rüsch EDGAR 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
- The Hudson RCI Sheridan $ETCO_2$ Uncuffed Tubes - K861454
- The Hudson RCI Sheridan LITA Cuffed Tracheal Tubes - K834463
- The Mallinckrodt Emergency Medical Tube (EMT) - 510(k) # Unknown

4. Description of the Device:

The Rüsch Edgar Tube will be offered in the Magill pattern in two (2) versions - cuffed and uncuffed. Cuffed versions 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 Edgar Tube consists of a clear endotracheal tube with a radiopaque stripe. The main tube is graduated with multiple centimeter markings to facilitate determination of intubated length. The instillation lumen is connected to a luer lock connector with cap by a tube that is color coded to prevent confusion with the cuff inflation line.

The Rüsch Edgar Tube will be available in a variety of sizes ranging from 2.5mm - 6.0mm uncuffed and 6.5mm - 10.0mm cuffed. Both versions will be available in 0.5mm increments.

5. Intended Use of the Device:

The Rüsch Edgar Tube is a sterile, single-use, oral/nasal tracheal tube intended to be used for airway management. The integral instillation system is indicated for drug instillation by the endobronchial route, anesthetic administration and gas monitoring.

6. Summary of Technological Characteristics:

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

Materials:

The Rüsch Edgar Tube is manufactured from the same materials (except for the instillation tube, the luer lock fitting and the cap which are non-body contact components), manufactured by the same processes and sterilized under the same conditions as the Rüsch Safety Tracheal Tubes which were in interstate commerce prior to May 28, 1976, the Rüsch AGT PVC Preformed Nasal Tracheal Tubes, K931163 and K931166 and the Rüsch Oral/Nasal (Safety Clear Plus™) Tracheal Tube, Cuffed, Magill/Murphy, Sterile - K993786.

The Rüsch Edgar Tube will differ from the predicate Rüsch Tracheal tube only in that it will have an integral instillation line, indicated for drug instillation and gas monitoring.

Size Range:

The Rüsch Edgar Tube will be available in a variety of sizes ranging from 2.5mm - 6.0mm uncuffed and 6.5mm - 10.0mm cuffed. Both versions will be available in 0.5mm increments.

The Hudson RCI Sheridan uncuffed tubes are available in sizes ranging from 2.0mm - 5.0mm. The Hudson RCI Sheridan cuffed tubes are available in sizes ranging from 6.0mm - 8.5mm. All versions are available in 0.5mm increments.

The Mallinckrodt uncuffed tubes are available in sizes ranging from 2.0mm - 5.5mm. The Mallinckrodt cuffed tubes are available in sizes ranging from 6.0mm - 8.5mm. All versions are available in 0.5mm increments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 1 2002

Mr. Rick Lykins
General Manager
Rüsch, International
Tall Pines Park
Jaffrey, New Hampshire 03452

Re: K021540
Trade/Device Name: Rüsch EDGAR Tube
Regulation Number: 21 CFR 868.5730
Regulation Name: Endotracheal or Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: May 10, 2002
Received: May 10, 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.

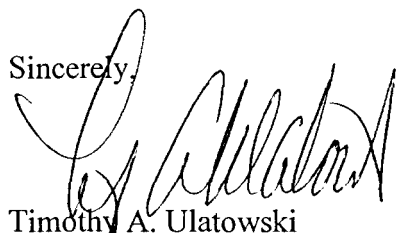
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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): K021540

Device Name: Rüsch Edgar Tube

Indications for Use:

The Rüsch Edgar Tube is a sterile, single-use, oral/nasal tracheal tube intended to be used for airway management. The integral instillation system is indicated for drug instillation by the endobronchial route, anesthetic administration and gas monitoring.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021540

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

(Optional Format 1-2-96)