AUG - 3 1999

K990619

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.**

Karenann J. Brozowski
Group Regulatory Affairs Director
Rüsch International
Tall Pines Park
Jaffrey, New Hampshire 03452

Telephone: (603) 532-7706
Facsimile: (603) 532-8211

Contact: Same as above

2. **Classification Name: Tube, Tracheal (with/without connector)**

Common Name: Tracheal Tube, or Endotracheal Tube

Proprietary Name: Rüsch Reinforced Endotracheal Tube Cuffed and Uncuffed of Murphy/Magill, sterile

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

The Rüsch Reinforced Endotracheal Tube is substantially equivalent to the Willy Rüsch Reinforced Tracheal Tube, Cuffed, Sheridan Reinforced Cuffed Tracheal Tube, SIMS/Portex Reinforced Cuffed Silicone Tracheal Tube and NCC/Mallinckrodt Reinforced Tracheal Tube Cuffed.

4. **Description of the Device.**

The Rüsch Reinforced Endotracheal Tube consists of a specially designed, clear PVC tube with stainless steel reinforcing spiral. The tube is graduated with multiple centimeter markings to allow easy determination of intubation length, and is terminated with a connector. An optional Murphy eye provides an alternative opening. This eye is the

difference between the Murphy (with eye) and the Magill (without eye) tracheal tube. The device is for nasal/oral use.

The Rüsch Reinforced Endotracheal tube, cuffed is fitted with a cuff, which is inflated through an inflation line and a lumen in the wall of the tube.

5. Intended Use of the Device

Rüsch Reinforced Endotracheal Tube is designated for oral or nasal intubation and are indicated for airway management. The product may be used to reduce the potential for kinking whenever an unusual positioning of the head or neck is required following intubation.

6. Summary of Technological Characteristics

The device is equivalent in design and intended use with Willy Rüsch Reinforced Tracheal Tube and alternative predicates. The products are spiral PVC tubes, cuffed and uncuffed, with or without (uncuffed) luer activated valve.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 1999

Ms. Karenann J. Brozowski
Group Regulatory Affairs Director
Rusch International
Tall Pines Park
Jaffrey, NH 03452

Re: K990619
Trade Name: Rusch Reinforced Endotracheal (or Tracheal) Tube Cuffed or Uncuffed, Murphy/Magill, Sterile
Regulatory Class: II
Product Code: BTR
Dated: April 30, 1999
Received: May 5, 1999

Dear Ms. Brozowski:

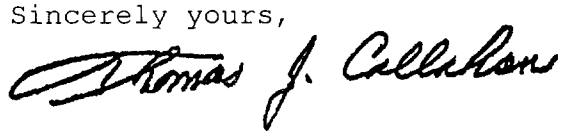
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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) 594-4586. 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 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/dsma/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: Rusch Reinforced Endotracheal (or Tracheal) Tube
Cuffed or Uncuffed, Murphy/Magill

Indications for Use:

Rusch Reinforced Endotracheal Tube is designated for oral or nasal intubation and are indicated for airway management. The product may be used to reduce the potential for kinking whenever an unusual positioning of the head or neck is required following intubation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joanne A Whitcomb

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990619

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)