FEB 2 2000

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

K993786

1. Submitter Name, Address:

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

Telephone: (603) 532-7706
Facsimile: (603) 532-8211
E-Mail: 73451.1040@compuserve.com
Contact: Same as above

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

Classification Name: Tube, Tracheal (w/wo Connector 73BTR)

Common/Usual Name: Tracheal Tube, or Endotracheal Tube

Proprietary Name: Rüsch Oral/Nasal (Safety Clear Plus™) Tracheal Tube, cuffed, Magill/Murphy, Sterile

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

The Rüsch Oral/Nasal Tracheal Tube, Cuffed, Magill/Murphy is substantially equivalent to Baxter Lo-Pro/Lo-Contour Tracheal Tube, Sheridan High Volume Tapered Low Pressure Cuff and Rüsch Safety Clear Plus Oral/Nasal Tracheal Tube, Cuffed, size 4.5-11.00mm.

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4. Description of the Device:

The Rüsch Oral/Nasal Tracheal Tube, Cuffed, Magill/Murphy consists of a clear PVC, implant tested, PVC tracheal tube with radiopaque ($BaSO_4$) stripe. The radiopaque stripe runs the entire length of the Tracheal Tube. The cuff is inflated via a valved pilot balloon using lock-tip or luer taper syringe. The main tube is graduated with multiple centimeter markings to allow easy determination of intubation length. A black positioning ring is present on the tube to aid in visualization of the tube. An optional Murphy eye provides an alternative opening. The device is for nasal and oral use.

5. Intended Use of the Device:

Rüsch Oral/Nasal Tracheal Tube, Cuffed, Magill/Murphy is a device inserted into a patient's trachea via the nose or mouth and used to maintain an open airway.

6. Summary of Technological Characteristics

The device is equivalent in design and intended use with Baxter Lo-Pro/Lo-Contour Tracheal Tube, Sheridan High Volume Tapered Low Pressure Cuff (K822082) and Rüsch Safety Clear Plus Oral/Nasal Tracheal Tube, Cuffed, size 4.5-11.00mm, K961837. The products are clear PVC tube, Cuffed, with/without eye, with luer activated valve.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2000

Ms. Karenann J. Brozowski
RUSH INTL.
Tall Pines Park
Jaffrey, NH 03452

Re: K993786
Rusch Oral/Nasal (Safety Clear Plus) Tracheal Tube, cuffed, Migill/Murphy Sterile
Regulatory Class: II (two)
Product Code: 73 BTR
Dated: November 3, 1999
Received: November 8, 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) 594-4648. 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/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon for

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K993786

Device Name: Rüsch Oral/Nasal (safety Clear Plus™) Tracheal Tube, Cuffed, Magill/Murphy

Indications For Use:

Rüsch Oral/Nasal Tracheal Tube, Cuffed, Magill/Murphy is a device inserted into a patient's trachea via the nose or mouth and used to maintain an open airway.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christy Foreman

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

Prescription Use ✓
(Per 21 CFR 801.109)

OR ~~Over-The-Counter~~ Use___

(Optional Format 1-2-96)