K972546

RÜSCH.
INTERNATIONAL
Group Regulatory Affairs
A Subsidiary of Teleflex Incorporated (USA)

Tall Pines Park
Jaffrey, NH 03452
(603) 532-7706
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APR 14 1998

510(k) SUMMARY

[As required by 21 CFR 807.92]

1. Submitter and Contact Person

James R. Whitney
Group Regulatory Affairs Associate
Rüsch International
Tall Pines Park
Jaffrey, NH 03452
Tel: (603)532 7706
Fax: (603)532 8211

2. Device set Name

Trade Name:

Rüsch Single Use Crystal Tracheostomy Tube set

Common Name:

Tracheostomy Tube

Classification Name:

Tube, Tracheostomy, and Tube Cuff
73 JOH; 21 CFR 868.5800; Class II medical device

3. Comparison Devices

Rüsch (Warne Surgical Products)
Crystal Tracheostomy Tube - Preamendment

Smiths Industries
D.I.C. & Portex Blue Line Tracheostomy Tubes - K934465

Bovina Medical Technologies
Cuffed Pediatric Tracheostomy Tubes - K913270, K914088

4. Description of Device Set

The Rüsch Single Use Crystal Tracheostomy Tube set consists of a polyvinyl chloride tube with a radiopaque stripe, terminated with a flange and connector. The tube is fitted with a high volume cuff inflated through a luer-activated valve, pilot balloon, inflation tube and a lumen in the wall of the main tube.

Inner cannulas made of low density polyethylene and specifically designed for use with this tube are individually sterile packed. These cannulas may be boxed with the tracheostomy tube and will be available separately.

5. Intended Use

The Rüsch Single Use Crystal Tracheostomy Tube is indicated for airway management of tracheostomized patients.

6. Summary of Technological Characteristics

The Rüsch Single Use Crystal Tracheostomy Tube Set has been developed from the Rüsch (formerly Warne Surgical Products) Crystal Tracheostomy Tube, which was in interstate commerce prior to May 28, 1976. The cumulative effect of developments, including modifications introduced to comply with the voluntary ISO 5366 standard, is thought to warrant this premarket notification.

The Rüsch Single Use Crystal Tracheostomy Tube Set will be available with and without an inner cannula, like the Smiths Industries (Portex) product and sizes from 3.0 to 11.0 mm.

7. Summary of Performance Data

Laboratory bench testing has been completed to demonstrate compliance with appropriate sections of ISO 5366.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 1998

Mr. James R. Whitney
Rüsch International
Tall Pines Park
Jaffrey, NH 03452

Re: K972546
Rüsch Crystal Tracheostomy Tube
Regulatory Class: II (two)
Product Code: 73 JOH
Dated: November 25, 1997
Received: January 15, 1998

Dear Mr. Whitney:

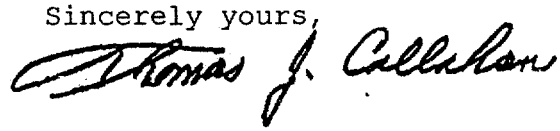
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

Premarket Notification "Indications for Use" Statement

510(k) Number (if known): K 972546

Device set Name: Rüsch Single Use Crystal Tracheostomy Tube Set

Indications for Use:

The Rüsch Single Use Crystal Tracheostomy Tube Set is indicated 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)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K 972546

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)