K964056

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

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(603) 532-7706
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OCT 10 1997

510(K) SUMMARY
ULTRATRACHEOFLEX®/TRACHEOFLEX® TRACHEOSTOMY KITS

Submitter Information/Contact Person:

Neil R. Armstrong
Group Regulatory Affairs Manager
Rüsch International
Tall Pines Park
Jaffrey NH 03452
Phone Number: (603) 532-7706
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Date 510(k) Summary Prepared: August 29, 1996

Name of the Device:

Trade or Proprietary Name: Rüsch UltraTracheoflex® Fenestrated Tracheostomy Kit - Cuffed

Rüsch Tracheoflex® Tracheostomy Kit - Uncuffed

Rüsch Tracheoflex® Fenestrated Tracheostomy Kit - Uncuffed

Common Name: Fenestrated or unfenestrated Tracheostomy Tube Kit - cuffed, or uncuffed fixed length, with connectors.

Classification Name: Tracheostomy tube and tube cuff, and accessories: 21 CFR 868.5800

Identification of Legally Marketed Device to which the Submitter Claim Equivalence:

The subject devices cuffed are substantially equivalent to the Rüsch UltraTracheoflex® Tracheostomy Kits legally marketed under K955564. These devices are also similar to the Portex Flexible D.I.C. Tracheostomy Tube found substantially equivalent under K934465.

The subject devices are similar or equivalent to the predicates in significant features, materials, dimensions, and intended use.

Description of the Subject Devices:

The Ultra Tracheoflex® Fenestrated Tracheostomy Set-Cuffed, Tracheoflex® Tracheostomy Set-Uncuffed, Tracheoflex® Fenestrated Tracheostomy Set-Uncuffed, are sterile, disposable, single use cuffed, or uncuffed fenestrated fixed length fenestrated tracheostomy tubes with a fixed flange. The kit may include a radiopaque tube, a tube obturator, a cough cap, a 15 mm airway connector, phonation value, a sealing cap, exchangeable inner cannulas, and a neck band. The inner cannula will be also available as a separate item.

These devices meet applicable portions of the following voluntary standards:

ISO 5366-1: Tracheostomy Tubes,Connectors for Tubes for Adults.

ISO 5366-2: Basic requirements for Tracheostomy Tubes for Adults.

ISO 5356: Anesthesia and Respiration Equipment, Conical Connectors, Cones and Sockets.

ISO 5361-5: Tracheal Tubes, Requirements and Tests for Cuffs and Tubes.

Intended Use of Subject Device

These tracheostomy tube kits intended for airway management in a tracheostomized patient.

Technological Characteristics of the Subject Devices

The 510(k) application devices and the predicates have the same technological characteristics except for:

1. The Tracheoflex® and the fenestrated Tracheoflex® tracheostomy tubes are not cuffed.

2. The Rüsch predicate is not fenestrated. The UltraTracheoflex® Fenestrated and the Tracheoflex® Uncuffed, Fenestrated are fenestrated tracheostomy tubes. The Portex D.I.C. tube is available fenestrated.

No clinical testing was completed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 1997

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

Re: K964056
Rüsch Ultra Tracheoflex Fenestrated Kit Cuffed, Uncuffed
Regulatory Class: II (two)
Product Code: 73 JOH
Dated: July 18, 1997
Received: July 21, 1997

Dear Mr. Whitney:

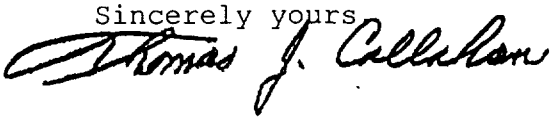
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 964056

Device Name: Rüsch UltraTracheoflex®/Tracheoflex® Tracheostomy Tube Kits (cuffed, fenestrated; uncuffed, unfenestrated; uncuffed, fenestrated)

Indications for Use:

The Rüsch UltraTracheoflex®/Tracheoflex® Tracheostomy Tube Kits are intended for use in 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)

Ath A. Ciarkowski

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K964056

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

Attachment 2