

Tall Pines Park
Jaffrey, NH 03452
(603) 532-7706
FAX (603) 532-8211 or 6108

JUN 28 1996

K955564

510(K) SUMMARY

ULTRA TRACHEOFLEX® TRACHEOSTOMY SET - CUFFED

Submitter Information:

Neil R. Armstrong
Group Regulatory Affairs Manager
Rüsch International
Tall Pines Park
Jaffrey, NH 03452
Phone Number: (603) 532-7706
Fax Number: (603) 532-8211

Date 510(k) Summary Prepared: October 10, 1995

Name of the Device:

Trade or Proprietary Name: Rüsch Ultra Tracheoflex®
Tracheostomy Set - Cuffed

Common Name: Tracheostomy Set-Cuffed, Fixed
length

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

Airway Connector: 21 CFR
868.5810

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

The Ultra Tracheoflex[®] Tracheostomy set cuffed is substantially equivalent to two products marketed by Rüsck prior to May 28, 1976: These are the Safetyflex[®] Tracheotomy Set available since April, 1974, and the Tracheoflex[®] Tracheotomy Set, available since April 1971. This device is 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[®] Tracheostomy Set-Cuffed is a sterile, disposable, single use cuffed tracheostomy tube with a fixed flange. The set includes a radiopaque tube, a tube obturator, a cough cap, a 15 mm airway connector, 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:

ASTM F1242-89, Standard Specification for Cuffed and Uncuffed Tracheal Tubes.

ISO 5366-1, Tracheostomy Tubes, Part 1, 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, Tracheal Tubes, Part 5: Requirements and Tests for Cuffs and Tubes.

Intended Use of Subject Device

The Rüsche Ultra Tracheoflex® Tracheostomy Set-Cuffed is a tracheostomy tube with accessories, intended for intubation through a surgical incision into the trachea, for the purpose of providing a patent airway.

Technological Characteristics of the Subject Devices

The subject device and the predicates have the same technological characteristics as the predicate devices except for:

1. The subject device's tube cuff is filled via a pilot balloon tube that ends in a spring (Bespak) valve. The Rüsche predicate devices have a balloon that ended in a capped luer. This technological improvement was made to aid in the prevention of the loss of cuff pressure due to the improper placement of the cap after cuff inflation.
2. The Rüsche predicate devices had a 15 mm airway connector permanently attached to the tube flange. The subject device has a ISO standard screw-luer fitting permanently attached. This allows a locking connections to a 15 mm airway connector, a cough cap, or other connectors as needed.

No clinical testing was completed.