SMITHS INDUSTRIES
Medical Systems

K962175

JAN 17 1997

SIMS Inc.
15 Kit Street
Keene, NH 03431
Telephone: (603) 352-3812
Fax: (603) 352-3703

H: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY

COMPANY INFORMATION

Smiths Industries Medical Systems, Inc.
15 Kit Street
Keene, NH
FAX: 603-357-5038
Timothy J. Talcott
Manager of Regulatory Affairs

PREPARATION DATE OF SUMMARY

June 3, 1996

TRADE NAME

PORTEX® Adjustable Flange Tracheostomy Tube

COMMON NAME

Tracheostomy Tube, with or without a cuff

CLASSIFICATION NAME

Class II, 73 JOH, 21 CFR 868.5800.

PREDICATE DEVICE

PORTEX® Blue Line™ Tracheostomy Tube and BIVONA Hyperflex™ Tracheostomy Tube Adjustable Neckflange

DESCRIPTION

The PORTEX® Adjustable Flange Tracheostomy Tubes are made of implant tested, polyvinyl chloride with compatible profile, high volume, low pressure cuff. Radiopaque material is incorporated into the full length of the Adjustable Flange Tracheostomy Tube. The tracheostomy tube has an adjustable neck flange and a bonded 15 mm connector. The cuff inflation line has an inflation indicator and a self sealing luer one-way valve.

INDICATIONS FOR USE

The PORTEX® Adjustable Flange Tracheostomy Tube is indicated for airway management of tracheostomized patients where the ability to adjust the depth of insertion may be advantageous.

TECHNOLOGICAL CHARACTERISTICS

Portex Blue Line Tracheostomy Tube -- The device is similar in construction and materials as the predicate device, Portex Blue Line Tracheostomy Tube (PVC extrusion), except for the adjustable flange. This flange is designed to be adjustable to accommodate patients with various distances from the skin to the trachea. The flange is made from Ethylene Vinyl Acetate Copolymer, rather than PVC. The materials of the other predicate device, BIVONA Hyperflex™ Tracheostomy Tube Adjustable Neckflange, are made of silicone with a stainless steel imbedded wire. This tube is designed to accommodate patients with various distances from the skin to the trachea, as is the proposed device.

SUMMARY OF PERFORMANCE DATA

Performance assessment was not required to demonstrate substantial equivalence of the proposed device to the predicate devices.

SUMMARY OF NONCLINICAL AND CLINICAL TESTS

A clinical evaluation was performed in Europe. The subjects were selected based on the following requirements: Inclusion criteria - patients requiring a tracheostomy for airway management, age of at lease 6 years, a minimum weight of 20Kg, and either male or female. Exclusion criteria - Tubes not to be used in patients during radiotherapy.

81 PORTEX® Adjustable Flange Tracheostomy Tubes were trialed, of which 58% were of the proposed device design.

There were very few negative comments, which seemed to be related closely to the investigators experience with competitive tubes. One comment which has been fully addressed before the commercial availability of the Adjustable Flange Tracheostomy Tube is the 15mm connector security. Every confidence should be gained in the security of the connector when fully inserted. In order to ensure customer confidence the 15mm connector is bonded into the tube.

CONCLUSION OF NONCLINICAL AND CLINICAL TESTS

The PORTEX® Adjustable Flange Tracheostomy Tube is a safe and effective product to use in cases of routine and special tracheostomy.

ADDITIONAL INFORMATION

None

Very truly yours,

Smiths Industries Medical Systems, Inc.

Timothy J. Talcott
Manager of Regulatory Affairs