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Internal Correspondence

K: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY:

COMPANY INFORMATION

Smiths Industries Medical Systems, Inc.
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PREPARATION DATE OF SUMMARY

January 30, 1996

TRADE NAME

SIMS PER-FIT™ Percutaneous Tracheostomy Kit with Portex® Tracheostomy Tube and Disposable Inner Cannula

COMMON NAME

Tracheostomy Tube with Disposable Inner Cannula

PRODUCT CLASS/CLASSIFICATION

Class II, 73 JOH, 21 CFR 868.5800.

PREDICATE DEVICE

Our current Percutaneous Tracheostomy Kit, K936133 and our current Disposable Inner Cannula, K903730 and K912124. Also, comparison is being made to the Cook Critical Care Ciaglia Percutaneous Tracheostomy Introducer Set.

DESCRIPTION

SIMS PER-FIT™ Percutaneous Tracheostomy Kit with Portex® Tracheostomy Tube and Disposable Inner Cannula

The SIMS PER-FIT™ Percutaneous Tracheostomy Kit with Portex® Tracheostomy Tube and Disposable Inner Cannula is designed to permit percutaneous insertion of a specifically designed tracheostomy tube. This single cannula Percutaneous Tracheostomy Tube has a radiopaque blue line and is constructed of biocompatible polyvinylchloride material and incorporates a tapered and beveled distal tube tip to facilitate insertion through the percutaneously dilated stoma site. The tracheostomy tube has a neck flange, an integral 15 mm connector, and a cuff which deflates to a low profile on the tube for a smooth transition during insertion. The cuff inflation line has a self sealing luer valve. The tracheostomy tube is supplied with a disposable inner cannula of the appropriate size. The Percutaneous Tracheostomy Kit comes with the necessary components for percutaneous tracheostomy tube insertion into a stoma created by serial dilation.

Disposable Inner Cannula

The Disposable Inner Cannula is made of polyethylene and is ethylene oxide sterilized. The cannula is designated as a single use disposable device for use only with the Portex Percutaneous Tracheostomy Tube.

Per-Fit™ Portex® Percutaneous Tracheostomy Tube

The Portex® Percutaneous Tracheostomy Tube is designed for insertion via the percutaneous route utilizing the **Per-Fit™** Percutaneous Tracheostomy Kit. The tracheostomy tube has a radiopaque blue line and is constructed of biocompatible polyvinylchloride material and incorporates a tapered and beveled distal tip to facilitate insertion through the percutaneously dilated stoma site. The tracheostomy tube features a flexible flange, an integral 15 mm connector, and a cuff that deflates to a low profile for a smooth transition during insertion. The cuff inflation line has a self sealing luer valve. The tracheostomy tube is supplied with a disposable inner cannula of the appropriate size. The tube is supplied with an obturator/dilator sized to match the outer tube and to facilitate insertion.

INDICATIONS FOR USE

SIMS PER-FIT™ Percutaneous Tracheostomy Kit with Portex® Tracheostomy Tube and Disposable Inner Cannula

The SIMS PER-FIT™ Percutaneous Tracheostomy Kit with Portex® Tracheostomy Tube and Disposable Inner Cannula is indicated for use in providing percutaneous temporary tracheal access for airway management.

Disposable Inner Cannula

The Disposable Inner Cannulae are indicated for use in maintaining airway patency of the outer cannula in the presence of thick tenacious secretions or when it is desirable to minimize the cleaning materials and the nursing time required. The Disposable Inner

Cannulae provide a means to protect against the risk of airway obstruction, contamination, and infection.

Per-Fit™ Portex® Percutaneous Tracheostomy Tube

The **Per-Fit™** Percutaneous Tracheostomy Tube is intended for use as a replacement tube for the percutaneous tracheostomy tube that is supplied in the **Per-Fit™** Percutaneous Tracheostomy Kit. It is intended to be used for replacement during the initial procedure or as a change-out tube following the procedure.

TECHNICAL CHARACTERISTICS

The SIMS PER-FIT™ Percutaneous Tracheostomy Kit with Portex® Tracheostomy Tube and Disposable Inner Cannula has the same technical characteristics as is currently marketed with our existing Percutaneous Tracheostomy Kit, K936133 and our current Disposable Inner Cannula, K903730 and K912124. The guidewire is equivalent to the guidewire supplied in our current device and the Cook Critical Care Ciaglia Percutaneous Tracheostomy Introducer Set.

CONCLUSION

The testing performed and comparison to the predicate devices demonstrate that the proposed device is safe and effective and is substantially equivalent to the predicate devices.

Very truly yours,

Smiths Industries Medical Systems, Inc.
dba Concord/Portex



Timothy J. Talcott
Manager of Regulatory Affairs