K980466

SMITHS INDUSTRIES
Medical Systems

SIMS Portex Inc.
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FEB 24 1998

K: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY:

COMPANY INFORMATION

SIMS Portex Inc.
10 Bowman Drive
Keene, NH 03431
(603) 352-3812
Contact: Timothy J. Talcott
Manager, Regulatory Affairs

PREPARATION DATE OF SUMMARY

February 4, 1998

TRADE NAME

PER-FIT™ Percutaneous Dilational Tracheostomy Kit with Specialty 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 PER-FIT™ Percutaneous Dilational Tracheostomy Kit with Specialty Tracheostomy Tube and Disposable Inner Cannula, K960429 and Cook Critical Care's Ciaglia Percutaneous Tracheostomy Introducer Set.

DESCRIPTION

The PER-FIT™ Percutaneous Dilational Tracheostomy Kit with Specialty 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.

INDICATIONS FOR USE

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

TECHNICAL CHARACTERISTICS

The PER-FIT™ Percutaneous Dilational Tracheostomy Kit with Specialty Tracheostomy Tube and Disposable Inner Cannula has the same technical characteristics as is currently marketed with our existing PER-FIT™ Percutaneous Dilational Tracheostomy Kit with Specialty Tracheostomy Tube and Disposable Inner Cannula, K960429 and Cook Critical Care's Ciaglia Percutaneous Tracheostomy Introducer Set. The "Dilator Stop" of the proposed modification is the same as the "Safety Ridge" of Cook Critical Care's guiding catheter.

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,

SIMS Portex Inc.

Timothy J. Talcott
Manager, Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 1998

Mr. Timothy J. Talcott
Manager, Regulatory Affairs
SIMS Portex, Inc.
10 Bowman Drive
P.O. Box 0724
Keene, NH 03431

Re: K980466
PER-FIT™ Percutaneous Dilational Tracheostomy Kit with Specialty Tracheostomy Tube and Disposable Inner Cannula
Regulatory Class: II (twō)
Product Code: 73 JOH
Dated: February 4, 1998
Received: February 6, 1998

Dear Mr. Talcott:

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

B: INTENDED USE OF DEVICE

510(k) Number (if known): Unknown

Device Name: PER-FIT™ Percutaneous Dilational Tracheostomy Kit with Specialty Tracheostomy Tube and Disposable Inner Cannula

Indications For Use:

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Bazaral (Reviewer)

Prescription Use X OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K980466