



SMITHS INDUSTRIES

Medical Systems

K972385

SIMS Inc.

15 Kit Street

Keene, NH 03431

Telephone: (603) 352-3812

Fax: (603) 352-3703

JAN 20 1998

J: 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, Regulatory Affairs

PREPARATION DATE OF SUMMARY

June 24, 1997

TRADE NAME

Fenestrated Flexible D.I.C. Tracheostomy Tube

COMMON NAME

Tracheostomy Tube, with or without a cuff

CLASSIFICATION NAME

Class II, 73 JOH, 21 CFR 868.5800.

PREDICATE DEVICE

Our Flexible D.I.C. Tracheostomy Tube, Fenestrated Blue Line™ Tracheostomy Tube, and Fenestrated D.I.C. Tracheostomy Tube. Also, Shiley's fenestrated low pressure cuffed tracheostomy tube and Boston Medical Products' Tracoe^{flex}® fenestrated tracheostomy tube.

DESCRIPTION

The Fenestrated Flexible D.I.C. Tracheostomy Tube is made of implant tested, polyvinyl chloride with compatible profile, high volume, low pressure cuff. Radiopaque material is incorporated into the full length of the Fenestrated Flexible D.I.C. Tracheostomy Tube. The cuff inflation line has an inflation

indicator and a self sealing luer one-way valve. The tracheostomy tube has three fenestrations on the radius of the tube.

INDICATIONS FOR USE

The Fenestrated Flexible D.I.C. Tracheostomy Tube is indicated for airway management of the tracheostomized patient for providing tracheal access where the use of a fenestration is desirable in order to allow for safe and effective weaning from mechanical ventilation or adjunctive airway support. With the cuff deflated, primary ventilation is allowed to be spontaneous through the fenestrations and around the main tube. This provides a means for phonation when the patient breaths through his/her upper airway. A red decannulation cap can be used to occlude the proximal end of the tracheostomy tube.

TECHNOLOGICAL CHARACTERISTICS

The location of the fenestrations are relocated to accommodate a greater percentage of the population. The location of the fenestrations has been determined based on a literature search taking into account the mean sagittal diameter and mean skin to trachea dimension.

SUMMARY OF PERFORMANCE DATA

Not required.

SUMMARY OF NONCLINICAL AND CLINICAL TESTS

Not required.

CONCLUSION OF NONCLINICAL AND CLINICAL TESTS

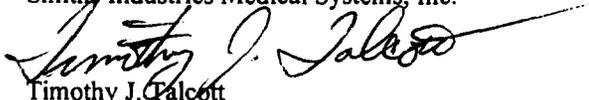
Not required.

ADDITIONAL INFORMATION

None

Very truly yours,

Smiths Industries Medical Systems, Inc.



Timothy J. Palcott

Manager of Regulatory Affairs



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 1998

Mr. Timothy J. Talcott
Smiths Industries Medical Systems, Inc.
10 Bowman Drive
P.O. Box 0724
Keene, NH 03431

Re: K972385
Fenestrated Flexible D.I.C. Tracheostomy Tube
Regulatory Class: II (two)
Product Code: 73 JOH
Dated: November 26, 1997
Received: December 2, 1997

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.

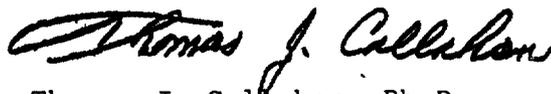
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Timothy J. Talcott

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

Page 1 of 1

510(k) Number (if known): Unknown

Device Name: Fenestrated Flexible D.I.C. Tracheostomy Tube

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Payne
(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K972385

Prescription Use

OR

Over-The-Counter Use