K081086

AUG 13 2008

SECTION 5:
510(k) SUMMARY

Trade Name: Portex® Blue Line® SACETT™ Suction Above the Cuff Tracheal Tube

Common Name: Endotracheal Tube
™

Classification Name: Tube, Tracheal (21 CFR 888.5730, Product Code BTR)

Contact Person:
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Equivalent to: Hi-Lo™ Evac Endotracheal Tube - K965132

Portex® Tracheal Tube – already marketed in the USA from 1976 under pre-amendment arrangement.

Portex® Blue Line® Ultra Suctionaid Tracheostomy Tube – K030570

Device Description: Single use Tracheal tube with integral suction line for lavage and evacuation above the cuff.

The product design is based upon a tracheal tube with the addition of a third (integral) lumen within the tube. The lumen terminates above the cuff via a 'notch' which enables the entrance (via suction) of secretions which have pooled above the cuff into the third (suction) lumen. Approximately half way along the tube length the suction lumen is joined to a suction line which is external to the main tube. The suction line is joined to the suction lumen in a similar manner to that of the joint between the inflation line and the inflation lumen. The distal (clinician) end of the suction line terminates in a connector which can be connected to either suction tubing or a syringe.

Intended Use:

Portex® Blue Line® SACETT™ is intended for oral intubation only for airway management of patients anticipated to require prolonged mechanical ventilation in critical care units. The product may be inserted in the emergency room or pre-hospital to avoid the need for re-intubation, SACETT™'s dorsal suction lumen allows drainage by continuous or intermittent suctioning of contaminated mucous and subglottis secretion that accumulate above the cuff.

Substantial Equivalence:

The Portex® Blue Line® SACETT™ Suction Above the Cuff Tracheal Tube has the same intended use as the Mallinckrodt Medical Hi-Lo™ Evac Endotracheal Tube.

The Portex® Blue Line® SACETT™ Suction Above the Cuff Tracheal Tube is composed essentially of the same materials as the Portex Tracheal Tube and the Portex® Blue Line® Ultra Suctionaid (BLUS) Tracheostomy Tube. The Portex® Blue Line® SACETT™ Suction Above the Cuff Tracheal Tube incorporates a number of design and performance characteristics from the Mallinckrodt Hi-Lo™ Evac Endotracheal Tube, the Portex® Tracheal Tube and the Portex® Blue Line® Ultra Suctionaid Tracheostomy Tube, including similar sterilisation and packaging processes.

The determination of substantial equivalence of the Portex® Blue Line® SACETT™ Suction Above the Cuff Tracheal Tube to the predicate devices was based on a comparison of device technological characteristics and materials of composition.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smiths Medical ASD, Incorporated
C/O Mr. John Tullett
Regulatory Affairs Manager
Smiths Medical International
Military Road
Hythe, Kent, United Kingdom CT216JL

AUG 13 2008

Re: K081086
Trade/Device Name: Portex® Blue Line® SACETT™ Suction above the Cuff Tracheal Tube
Regulation Number: 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: August 1, 2008
Received: August 1, 2008

Dear Mr. Tullett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4:
INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name:	Portex® Blue Line® SACETT™ Suction Above the Cuff Tracheal Tube
Indications for Use:	Portex® Blue Line® SACETT™ is intended for oral intubation only for airway management of patients anticipated to require prolonged mechanical ventilation in critical care units. The product may be inserted in the emergency room or pre-hospital to avoid the need for re-intubation, SACETT™'s dorsal suction lumen allows drainage by continuous or intermittent suctioning of contaminated mucous and subglottis secretion that accumulate above the cuff.

Prescription Use X AND/ OR Over-The-Counter Use

(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091086