K083119

SECTION 5:
510(k) SUMMARY

JUN 26 2009

Trade Name: Portex® Tracheal Tube

Common Name: Tracheal Tube

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

Contact Person:
Brian Farias, RAC
Regulatory Affairs Manager
Smiths Medical North America
10 Bowman Drive
Keene, NH 03431
Tel: + 1 603-352-3812, ext 2493
Fax: +1 603-355-8157
www.smiths-medical.com
E-Mail: brian.farias@smiths-medical.com

Date: 07, October 2008

Equivalent to: Well Lead Aircare™ Endotracheal tube (K042683)

Device Description: A range of sterile, single use tracheal tubes for oral and/or nasal intubation intended for airway management. Manufactured from clear polyvinyl chloride (PVC) incorporating the following features:

- Thermosensitive materials with sufficient initial rigidity for intubation which then conforms to the individuals respiratory tract at body temperature ensuring minimum trauma.
- Radio-opaque Blue Line® to confirm correct tube placement by X-ray
- All Portex® tracheal tubes are packed with a 15mm connector conforming to ISO5356
- Sterile unless the unit pack is opened or damaged
- Cuffed tracheal tubes are designed with a high volume tapered low pressure cuff and all have an attached pilot balloon with a one way luer valve
- Smooth Murphy eye
- As a reference during intubation, the tracheal tubes have depth marks in centimetres which indicates the distance to distal tip.

Intended Use: Portex® tracheal tubes are intended for oral and/or nasal intubation for airway management. Expert clinical judgement should be exercised in the selection of the appropriate tracheal tube size and style for an individual patient. For adult, Paediatric excluding neonatal and infant use.

SECTION 4:
INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: Portex® Tracheal Tube

Indications for Use: Portex® tracheal tubes are intended for oral and/or nasal intubation for airway management. Expert clinical judgement should be exercised in the selection of the appropriate tracheal tube size and style for an individual patient. For adult, Paediatric, excluding neonatal and infant use.

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)

SECTION 11:
EXECUTIVE SUMMARY

A. Description of the Device

A range of sterile, single use tracheal tubes for oral and/or nasal intubation intended for airway management. Manufactured from clear polyvinyl chloride (PVC) incorporating the following features:

- Thermosensitive materials with sufficient initial rigidity for intubation which then conforms to the individuals respiratory tract at body temperature ensuring minimum trauma.
- Radio-opaque Blue Line® to confirm correct tube placement by X-ray
- All Portex® tracheal tubes are packed with a 15mm connector conforming to ISO5356
- Sterile unless the unit pack is opened or damaged
- Cuffed tracheal tubes are designed with a high volume tapered low pressure cuff and all have an attached pilot balloon with a one way luer valve
- Smooth Murphy eye
- As a reference during intubation, the tracheal tubes have depth marks in centimetres which indicates the distance to distal tip.

B. Indications for Use

Portex® tracheal tubes are intended for oral and/or nasal intubation for airway management. Expert clinical judgement should be exercised in the selection of the appropriate tracheal tube size and style for an individual patient. For adult, Paediatric excluding neonatal and infant use.

C. Compliance with relevant standards

The products conform to the relevant requirements of the ISO 5361:1999 Anaesthetic and respiratory equipment - Tracheal tubes and connectors. Evidence of this compliance is supplied in Exhibit F

D. Comparison with Predicate Devices

A comparison of Portex® Tracheal Tube with the predicate device is presented in Table 2. This comparison supports a claim of substantial equivalence by virtue of the similarity between the Portex® Tracheal Tube and the identified predicate in terms of indications for use, design characteristics, presentation, method of sterilization, materials of composition, packaging and performance characteristics.

SECTION 13:
SUBSTANTIAL EQUIVALENCE

A. Predicate Devices

The Portex® Tracheal Tube is substantially equivalent to the existing marketed Class II device identified in Table 3. The predicate device has been cleared by FDA for commercial distribution in USA via pre-amendment route.

Table 3 – Predicate device for Portex® Tracheal Tube

Device Trade Name	Product Codes	510(k) Submitter	510(k) Number(s)
Well Lead Aircare™ Endotracheal tube	100/100/050-095	Well Lead Medical	K042683

B. Substantial Equivalence Rationale

1. Indications for Use

The indications for use of the Portex® Tracheal Tube are intended for oral and/or nasal intubation for airway management. Expert clinical judgement should be exercised in the selection of the appropriate tracheal tube size and style for an individual patient. For adult, Paediatric excluding neonatal and infant use.

Tracheal tube maximum period of use 29 days.

The above indications for use are substantially equivalent to that of the predicate device, Well Lead Aircare™ Endotracheal tube (K042683).

2. Substantial Equivalence

i) Device Design and Material Composition

The device design and material composition equivalence data between the Portex® Tracheal Tube and the predicate device is provided in table 4.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2009

Smiths Medical ASD, Incorporated
C/O Mr. Ian Stace
Principal Project Engineer
Smiths Medical International Limited
Boundary Road
Hythe, Kent
UNITED KINGDOM CT216JN

Re: K083119
Trade/Device Name: Portex® Tracheal Tube
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: June 11, 2009
Received: June 16, 2009

Dear Mr. Stace:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Susan Runner, D.D.S., M.A.
Acting 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: K083119

Device Name: Portex® Tracheal Tube

Indications for Use: Portex® tracheal tubes are intended for oral and/or nasal intubation for airway management. Expert clinical judgement should be exercised in the selection of the appropriate tracheal tube size and style for an individual patient. For adult, Paediatric, excluding neonatal and infant use.

Prescription Use__X__ (Per 21 CFR 801 Subpart D) AND/ OR Over-The-Counter Use _____ (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: K083119