K032412

JAN 2 6 2004

Portex Ltd. PVC, Single Use Reinforced, Oral/Nasal Endotracheal Tube.
510(K) Notification

SECTION 5.0 : 510K SUMMARY

DATE SUBMITTED: **16 June 2003**

SUBMITTER:
Portex Ltd
Hythe
Kent
England, CT21 6JL

CONTACT PERSON:
Mr Steve Ogilvie,
Regulatory and Scientific Affairs Director,
Portex Ltd,
Military Road,
Hythe, Kent, England. CT21 6DB
Phone 00 44 (0)1303 208011
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DEVICE NAME:
Reinforced Tracheal tubes Cuffed
Reinforced Tracheal tubes Uncuffed

COMMON NAME AND CLASSIFICATION:
Reinforced Tracheal Tube. Class II BTR, 21 CFR 868.5730

PREDICATE DEVICES:

Device comparison

- Predicate 1: Mallinckrodt Tracheal tube Uncuffed already marketed in the USA under K841872
- Predicate 2: Rüsch Tracheal tube Cuffed already marketed in the USA under K990619
- Predicate 3: Portex Blue Line Tracheal tube PVC Cuffed (100/199) already marketed in the USA from 1976 under pre-amendment arrangement.
- Predicate 4: Euromedical Reinforced Endotracheal Tube already marketed in the USA under K962389
- Predicate 5: Blue Line Adjustable flange tracheostomy tube (AFT) already marketed in the USA under K962175
- Predicate 6. Blue Line Ultra Tracheostomy tube already marketed in the USA under K030570.

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DEVICE DESCRIPTION:

Single use.
A Tracheal tube with additional metal wire spiral reinforcement to provide kink-resistance.
This type of product is typically used during operations where a high degree of flexibility is required from the tube, for instance prone position, head and neck surgery, oral surgery.

The plastic material and the spring allow the tube to be easily bent in all directions. The steel reinforcement maintains the patency of the lumen.

The Portex Ltd PVC, Single-use Reinforced tracheal tube is available in cuffed and uncuffed variants. The cuff is intended to provide a seal against the trachea, ensuring that inspiratory and expiratory gasses are routed through the tube and not allowed to escape to the patients upper airway, thus preventing loss of ventilation / anaesthetic and nebulised drugs, and reducing the likelihood of any aspirated stomach contents from entering the lungs. Uncuffed tubes are used mainly for paediatric patients or when patients require less protection from loss of ventilation / anaesthetic and nebulised drugs and or stomach aspiration.

The reinforced tracheal tube (Cuffed Murphy eye) is available in sizes 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 and 9.5mm only.
The reinforced tracheal tube (Uncuffed) is available in sizes 3.0, 3.5, 4.0, 4.5 and 5.0mm only.

INTENDED USE:

(Include significant Clinical Performance requirements)
The Portex Reinforced Tracheal Tubes (cuffed and uncuffed) are designed for oral or nasal intubation for airway management during anaesthesia. The product may be used where the patient's neck is likely to be moved or flexed or the patient is in the prone position so that a non-reinforced tracheal tube might become kinked.

TECHNOLOGICAL CHARACTERISTICS OF PROPOSED VERSUS PREDICATE DEVICES:

The proposed device is substantially equivalent to Predicate device 1 - Mallinckrodt Tracheal tube Cuffed/Uncuffed (clear PVC), in all aspects except the following:

- **Reinforced tube with (Murphy eye).** The reinforced tracheal tube with additional metal wire spiral reinforcement for the proposed device is identical in material composition to the tubing used in Predicate 4- Euromedical reinforced endotracheal tube. The proposed device tube has a straight profile which is identical to the profile in Predicate 2.

SECTION 5.0 : 510K SUMMARY

- **Cuff.** The cuff for the proposed device is identical in material composition and to that of Predicate 6.

- **The print markings.** The print ink for the proposed device is identical in composite to the ink used for Predicate 6. The print layout for the proposed device displays similar information as the layout on Predicate 3.

- **Inflation line and pilot balloon.** Both the proposed device and Predicate 6's material composite for the inflation line and pilot balloon is identical. The pilot balloon is identically marked.

- **Connector.** The proposed device and Predicate 5 share the same material composition, moulded in natural Cyrolite. The proposed device connector spigot is solvent bonded to the tube, (substantially equivalent to Predicate 1), which allows the distal end to sit flush against the butt of the metal spiral preventing the tube from kinking.

PERFORMANCE / CLINICAL DATA:

Performance data for the proposed device is shown in Section 8.0 Performance.

CONCLUSION:

Comparison of the proposed device to the predicate devices supports the conclusion that the proposed device is substantially equivalent in safety and effectiveness in its intended use to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 6 2004

Mr. Steve Ogilvie
Regulatory and Scientific Affairs Director
Portex Ltd.
Military Road
Hythe, Kent
England CT21 6DB

Re: K032112
Trade/Device Name: Portex Reinforced Tracheal Tube (Cuffed and Uncuffed)
Regulation Number: 868.5730
Regulation Name: Tracheal tube
Regulatory Class: II
Product Code: BTR
Dated: not dated
Received: October 28, 2003

Dear Mr. Ogilvie:

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.

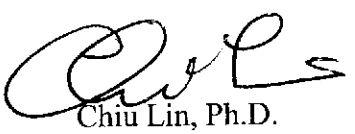
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



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

Enclosure

Portex Ltd. PVC, Single Use Reinforced, Oral/Nasal Endotracheal Tube.
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SECTION 4.0: STATEMENT OF INDICATION FOR USE

510(K) Number (if known): K032112

DEVICE NAME:

Reinforced Tracheal Tubes Cuffed
Reinforced Tracheal Tubes Uncuffed

INDICATIONS FOR USE:

1. The Portex Reinforced Tracheal Tubes (cuffed and uncuffed) are designed for oral or nasal intubation for airway management during anaesthesia. The product may be used where the patient's neck is likely to be moved or flexed or the patient is in the prone position so that a non-reinforced tracheal tube might become kinked.

Prescription Use **YES** (Part 21 CFR 801 Subpart D) *AND/OR* Over-The-Counter Use **NO** (21 CFR 807 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: K032112