K030381

AUG 27 2003

Portex Ltd. Blue Line Ultra Tracheostomy Kits.
510(K) Notification

SECTION 5.0 : 510K SUMMARY

DATE SUBMITTED: 22 August 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
Fax 00 44 (0)1303 262798

DEVICE NAME: Blue Line Ultra Tracheostomy Tube

COMMON NAME AND CLASSIFICATION: Tracheostomy tube. Class II BTO, 21 CFR 868.5800

PREDICATE DEVICES:

- Portex Inc Flexible D.I.C Tracheostomy tube, already marketed in the USA under K912124
- Shiley Low Pressure Cuffed Tracheostomy Tube with Reusable Inner Cannula, already marketed in the USA under K811033.
- Portex Inc. Percutaneous Dilatory tracheostomy Kit with Speciality tracheostomy Tube, already marketed in the USA under K980466
- Portex Inc Steri-Cath Closed Ventilation Suction System already marketed in the USA under K923559

DEVICE DESCRIPTION:

The Blue Line Ultra (BLU) tracheostomy tube provides an airway to the patients lungs when the upper airway / larynx / pharynx or oral & nasal routes are occluded or compromised due to traumatic injury, illness, or during surgery, and is elective for long term ventilated patients. The tube can be used for ventilated, or spontaneously breathing patients.

The BLU is available in sizes 6.0, 7.0, 7.5, 8.0, 8.5 and 9.0mm only.

BLU is available in cuffed and uncuffed variants. The cuff provides a seal against the trachea, ensuring that inspiratory and expiatory 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 when patients require less protection from loss of ventilation / anaesthetic and nebulised drugs and or stomach aspiration.

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The outer tube can be used with or without an inner cannula. The inner cannula lines the bore of the outer tube, and can be removed, cleaned and replaced to ensure that the bore of the tube is kept patent.

The BLU is supplied pre-loaded onto an obturator. The obturator reduces the risk of the distal end of the product from damaging the trachea upon insertion. The obturator has an internal pathway for a guide wire, so that a guide wire can be used to help position the tube through the stoma site for tube change insertion.

The BLU tracheostomy tube is packed in several kit variants to suit clinician preferences. Each kit contains a tracheostomy tube holder, an inner cannula cleaning brush, disconnection wedge and a patient notes label. The change kit includes a tube change j tip guide wire. This wire is used to help place a second tracheostomy tube in a pre-existing stoma when the first tube needs to be changed. Each kit is individually packed in a blister and shelf carton (tracheostomy tube holder and cleaning bush packed outside of the blister in a polyethylene bag), and the products are sterile by ETO.

Replacement Blue Line Ultra inner cannula are available in packs of 20 or 50. The cannula are individually packed in a blister to maintain sterility, and contained within a shelf carton. The inner cannula lines the bore of the outer tube, and can be removed, cleaned and replaced to ensure that the bore of the tube is kept patent.

INTENDED USE:

Portex Blue Line Ultra Tracheostomy Tube is indicated for airway maintenance of tracheostomised patients.

TECHNOLOGICAL CHARICTUREISTICS OF PROPOSED VERSUS PREDICATE DEVICES:

- The proposed device is substantially equivalent to Predicate device 1 - Portex Inc Flexible D.I.C Tracheostomy tube (K912124), in all aspects except the following:
    - **Inner cannula.** The basic design and materials of the inner cannula of Predicate 1 and the proposed device are substantially equivalent. However, the inner cannula of Predicate 1 is disposable, where as the inner cannula of the proposed device can be removed from the tracheostomy tube, cleaned and replaced. The re-useable feature of the proposed device's inner cannulae is compared to Predicate 2.
    - **Tube change guide wire.** The tube change guide wire is an additional component to Predicate 1. This component will be compared to predicate device 3.
    - **Disconnection Wedge.** The disconnection wedge is an additional component to Predicate 1. This component will be compared to predicate device 4.
- The re-useable feature of the proposed device's inner cannulae is substantially equivalent to Predicate 2 - Shiley Low Pressure Cuffed Tracheostomy Tube with Reusable Inner Cannula (K811033). Note, only the reusable nature of the inner cannula is compared.
- The tube change guide wire of the proposed device is substantially equivalent to Predicate 3 - Portex Inc. Percutaneous Dilatory tracheostomy Kit with Speciality tracheostomy Tube (K980466) Note, only the tube change guide wire is compared.

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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

AUG 2 7 2003

Mr. Steve Ogilvie
Regulatory and Scientific Affairs Director
Portex Limited
Military Road
Hythe, Kent
ENGLAND CT21 6DB
United Kingdom

Re: K030381
Trade/Device Name: Blue Line Ultra Tracheostomy Tube
Regulation Number: 868.5800
Regulation Name: Tracheostomy Tube and tube Cuff
Regulatory Class: II
Product Code: BTO
Dated: May 30, 2003
Received: June 2, 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,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Portex Ltd . Blue Line Ultra Tracheostomy Kits,
510(K) Notification

Section 4.0: STATEMENT OF INDICATION FOR USE

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Device Name: Portex Blue Line Ultra Tracheostomy Tube

Indications for use:

'Portex Blue Line Ultra Tracheostomy Tube is indicated for airway maintenance of Tracheostomised patients'

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

510(k) Number: K030381

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Concurrence of CDRH, Office of Device Evaluation (ODE)