Smiths Medical: Portex Percutaneous Dilation Tracheostomy kit with Serial Dilators or Single Stage Dilators, Blue Line Ultra Tracheostomy Tube and Introducer
510(K) Notification

K041348

JUL 1 3 2004

SECTION 5.0 : 510K SUMMARY

DATE SUBMITTED: 6th May 2004

SUBMITTER:

Smiths Medical
Hythe
Kent
England, CT21 6JL

CONTACT PERSON:

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DEVICE NAME:

Portex "Ultraperc" Percutaneous Dilation Tracheostomy kit with Serial Dilators or Single Stage Dilator, Blue Line Ultra Tracheostomy Tube and Introducer.

COMMON NAME AND CLASSIFICATION:

Percutaneous Dilation Tracheostomy kit with Serial Dilators. Class II BTO, 21 CFR 868.5800

PREDICATE DEVICES:

1. Portex Ltd: Portex Percutaneous Dilation Tracheostomy Kit with Serial Dilators, already marketed in the USA under K022212
2. Portex Ltd: Portex Percutaneous Dilation Tracheostomy Kit with Single Stage Dilator already marketed in the USA under K040014
3. Portex Ltd: Blue Line Ultra Tracheostomy Tube kits, already marketed in the USA under K030381
4. Portex Inc. Percutaneous Dilatory tracheostomy Kit with Speciality tracheostomy Tube (Perfit) already marketed in the USA under K980466
5. Rusch Percuquick set for percutaneous dilation tracheostomy already marketed in the USA under K011210
6. Shiley Low Pressure Cuffed tracheostomy tube already marketed in the USA under K880247

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DEVICE DESCRIPTION:

The Portex "Ultra Perc" single use Percutaneous Dilation Tracheostomy Kits allow the percutaneous insertion of a tracheostomy tube using either a serial (sequential) or single (one stage) circumferencial dilatational Seldinger guidewire technique.
Kits are supplied with a Portex Blue Line Ultra Tracheostomy Tube and introducer.
The kits are intended for use in a controlled setting such as an Intensive Care Unit or operating room with the assistance of trained personnel. A minimum of 2 operators are required – one to maintain the patient's airway, anaesthesia, breathing and circulation, and the other to perform the procedure.

The Portex Percutaneous Dilation Tracheostomy kit with Serial Dilators or Single Stage Dilator, Blue Line Ultra Tracheostomy Tube and Introducer, are available in sizes 7.0, 8.0 and 9.0mm only.

INTENDED USE:

The Portex "Ultra Perc" Percutaneous Dilation Tracheostomy kit with Serial Dilators or Single Stage Dilator, Blue Line Ultra Tracheostomy Tube and Introducer are indicated to create a percutaneous dlilational tracheostomy using guidewire dilators and components of this kit that allow for tracheal access for airway management.

TECHNOLOGICAL CHARICTERISTICS OF PROPOSED VERSUS PREDICATE DEVICES:

- The proposed device is equivalent to Predicate devices 1 & 2- Portex Ltd: Portex Percutaneous Dilation Tracheostomy Kits already marketed in the USA under K022212 and K040014 and Predicate 3 - Portex Ltd: Blue Line Ultra Tracheostomy Tube kits already marketed in the USA under K030381in all aspects except for the following:
    - **Tracheostomy tube Introducer.** The proposed device has a Tracheostomy tube Introducer that allows for the placement of the Blue Line Ultra Tracheostomy tube into the patients trachea. The curvature and materials of the Introducer will be compared with the Single Stage Dilator of Predicate 2 and the obturator of Predicate 3. The handle will be compared to he Single Stage Dilator of Predicate 2 and the Obturator/Introducer of Predicate 4

PERFORMANCE / CLINICAL DATA:

Performance data for the proposed device is shown in section 8.0 Performance. Clinical data is provided in Appendix 2

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

JUL 1 3 2004

Mr. Barry Smith
Regulatory Affairs Manager
Smiths Medical, International Limited
Military Road
Hythe, Kent, CT21 5BN
ENGLAND

Re: K041348
Trade/Device Name: Portex "Ultraperc" Percutaneous Dilation Tracheostomy Kit
Regulation Number: 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: JOH
Dated: May 6, 2004
Received: May 20, 2004

Dear Mr. Smith:

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

Smiths Medical : Portex Percutaneous Dilation Tracheostomy kit with Serial Dilators or Single Stage Dilator, Blue Line Ultra Tracheostomy Tube and Introducer
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SECTION 4.0: STATEMENT OF INDICATIONS FOR USE

Document 1

DEVICE NAME:

Portex "Ultraperc" Percutaneous Dilation Tracheostomy kit with Serial Dilators or Single Stage Dilator, Blue Line Ultra Tracheostomy Tube and Introducer.

INDICATIONS OF USE:

The Portex Percutaneous Dilation Tracheostomy kit with Serial Dilators or Single Stage Dilator, Blue Line Ultra Tracheostomy Tube and Introducer are indicated to create a percutaneous dilational tracheostomy using guidewire dilator/s and components of these kits that allow for tracheal access for airway management for use in adults only.

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: K041348