ATTACHMENT F: SUMMARY OF SAFETY AND EFFECTIVENESS

FEB 1 3 2004

K040014

510k SUMMARY:

COMPANY INFORMATION:

Portex Ltd,
Hythe,Kent.
England CT21 6DB

CONTACT: Barry Smith
Regulatory Affairs Manager

PREPARATION DATE OF SUMMARY:
16/12/03

TRADE NAME
Percutaneous Dilation Tracheostomy Kit with Single Stage Dilator, and Soft Introducers for Sizes 7, 8 & 9mm tubes **only, without** Tracheostomy Tube

COMMON NAME
Percutaneous Tracheostomy Kit

PRODUCT CLASS/CLASSIFICATION
Class II 73 JOH, 21 CFR 868.5800

PREDICATE DEVICES
The proposed device, the "Portex Percutaneous Dilation Tracheostomy Kit with Serial Dilators for Sizes 7, 8 & 9mm tubes **only, without** Tracheostomy Tube" (k022212)

DESCRIPTION:

The new kit is designed to permit percutaneous creation of a tracheostomy stoma and subsequent insertion of a size 7, 8 or 9mm tracheostomy tube. It employs the well understood and established procedure for dilating a stoma and introducing the tracheostomy tube using the Seldinger over a guide wire system. (Ref Portex Per-fit™ kit k980466 and Portex UltraPerc serial dilator kit k022212.

The kit contains all of the standard components to which the user are accustomed: scalpel, needle and cannula, syringe, guidewire, guiding catheter, Gauze pads, short pre-dilator, dilator system, and tracheostomy tube introducers.

The kit differs from the above two kits in that it employs a single tapered dilator to replace the multiple serial dilators.

The packaging is the same as that used in k022212. It is designed with an outer blister, which contains an inner tray. The tray layout is designed to present the user with the components in the order of use.

Each pack is EO sterilised and individually packed in a carton together with the directions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2004

Mr. Barry Smith
Portex Limited
Regulatory Affairs Manager
Hythe, Kent
ENGLAND CT21 6DB

Re: K040014
Trade/Device Name: Percutaneous Dilation Tracheostomy Kit with Single Stage Dilator, and Soft Introducer for Sizes 7, 8 & 9mm Tubes Only, without Tracheostomy Tubes
Regulation Number: 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: JOH
Dated: December 16, 2003
Received: January 23, 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.

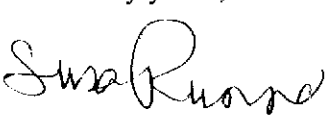
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



for 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

Indications for Use

510(k) Number (if known): Not known

Device Name: "Portex Percutaneous Dilation Tracheostomy Kit with Single Stage Dilator, and Soft Introducers for Sizes 7, 8 and 9mm tubes only. Without Tracheostomy Tube"

Indications for Use: "To create a percutaneous dilational tracheostomy using guidewire, single stage dilator and components of this product which allows for tracheal access for airway management."

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 OF NEEDED)

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

510(k) Number: K040014

Concurrence of CDRH, Office of Device Evaluation (ODE)