510k SUMMARY

MAR 21 2003

K022212

COMPANY INFORMATION:

Portex Ltd,
Hythe,Kent.
England CT21 6DB

Contact: Steve Ogilvie
Regulatory and Scientific Affairs Director

PREPARATION DATE OF SUMMARY:

10th February 2003

TRADE NAME

Percutaneous Dilation Tracheostomy Kit with Serial Dilators/Introducers for 7, 8 and 9mm tubes **only, without** Tracheostomy Tube (REF 100/566/000)

COMMON NAME

Percutaneous Tracheostomy Kit

PRODUCT CLASS/CLASSIFICATION

Class II 73 JOH, 21 CFR 868.5800

510k SUMMARY

PREDICATE DEVICES

Main Product Predicates:

- Rusch "PercuQuick Set" Percutaneous Tracheostomy Kit." Legally marketed in the USA under K011210
- Portex "Per-Fit Percutaneous Tracheostomy Kit" Legally marketed in the USA under K936133

Kit Component/Element Predicates:

Component/Element	Predicate
Hydrophilic coating for Serial Dilators/Introducers	Mallinckrodt "Finch" and "Copperhead" Percutaneous Transluminal Angioplasty Catheters already marketed in the USA under K983830
Scalpel	Maersk/Paragon Single Use Scalpel already sold into USA under device listing R027050.
Syringe	ASIK 'ONCE' Syringe already marketed in the USA under K852444
Guidewire materials	TFX guidewire already marketed in the USA under K963320
14G Needle and Cannula materials	Wallace IV Cannula already marketed in the USA under K932946
14Fr Pre-dilator materials	Base Polymer – Portex Adjustable Flange Tracheostomy tube already marketed in the USA under K962175. Colourant – Portex Y-Cann already marketed in the USA under K032047

DESCRIPTION:

The new kit is designed to permit percutaneous creation of a tracheostomy stoma for subsequent insertion of a size 7, 8 or 9mm tracheostomy tube.
The kit contains all of the standard components to which the users are accustomed from use of the Rusch predicate device: scalpel, gauze swabs, needle and cannula, syringe, guidewire, guiding catheter, short pre-dilator and set of serial dilators which are also used for introduction of the tracheostomy tube.

510k SUMMARY

INDICATIONS FOR USE:

"To create a percutaneous dilational tracheostomy using guidewire, dilators, and components of this product which allows for tracheal access for airway management."

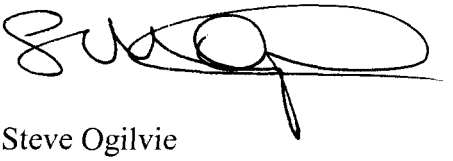
TECHNICAL CHARACTERISTICS:

Percutaneous Dilation Tracheostomy Kit with Serial Dilators/Introducers for 7, 8 and 9mm tubes **only, without** Tracheostomy Tube (REF 100/566/000) has the same technical characteristics as the currently marketed Rusch "PercuQuick Set" Percutaneous Tracheostomy Kit." K011210. Where necessary, the Portex "Per-Fit Percutaneous Tracheostomy Kit" K936133 is used as a predicate for specific features and/or characteristics.

CONCLUSION

The testing performed and comparison to predicate devices demonstrate that the proposed device is safe and effective and substantially equivalent to the predicate devices.

For Portex Ltd.



Steve Ogilvie

Regulatory and Scientific Affairs Director

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2003

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

Re: K022212
Trade/Device Name: Percutaneous Dilation Tracheostomy Kit (Serial Dilators)
Regulation Number: 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: JOH
Dated: February 13, 2003
Received: February 24, 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 (21 CFR Part 807); 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 the labeling regulation, please contact the Office of Compliance at (301) 594-__. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 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

510(k) Number (if known): K022212

Device Name: Portex Percutaneous Dilatiational Tracheostomy Kit

Indications for Use:

To create a percutaneous dilational tracheostomy using guidewire, dilators, and components of this product which allows for tracheal access for airway management.

Approved: 12/Feb/03

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

3/28/2003

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

510(k) Number: K022212