K031057

JUL 18 2003

Portex, Inc.
10 Bowman Drive
Keene NH 03431 USA
Tel 603 352 3812

K: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY:

COMPANY INFORMATION

Portex, Inc.
10 Bowman Drive
Keene, NH 03431
(603) 352-3812
Contact: Timothy J. Talcott
Director, Regulatory Affairs

PREPARATION DATE OF SUMMARY

April 2, 2003

TRADE NAME

PER-FIT™ Percutaneous Dilational Tracheostomy Kit with Specialty Tracheostomy Tube and Disposable Inner Cannula

COMMON NAME

Tracheostomy Tube with Disposable Inner Cannula

PRODUCT CLASS/CLASSIFICATION

Class II, 73 JOH, 21 CFR 868.5800.

PREDICATE DEVICES

Predicate 1: Our current PER-FIT™ Percutaneous Dilational Tracheostomy Kit with Specialty Tracheostomy Tube and Disposable Inner Cannula, K980466[K960429]. This is the main predicate device, cited for materials/biocompatibility and for most design characteristics.

Predicate 2: Our DIC (Disposable Inner Cannula) Tracheostomy Tube, K934465[K903730].
This predicate device is cited, in conjunction with Predicate 1 above, for the tube/inner cannula shape and distal tip geometry.

Predicate 3: The Rusch 'PercuQuick® Dilatator Set', K011210. This predicate device is cited for the obturator angled tip.

DESCRIPTION

The PER-FIT™ Percutaneous Dilational Tracheostomy Kit with Specialty Tracheostomy Tube and Disposable Inner Cannula is designed to permit percutaneous insertion of a specifically designed tracheostomy tube. This single cannula Percutaneous Tracheostomy Tube has a radiopaque blue line and is constructed of biocompatible polyvinylchloride material and incorporates a tapered and beveled distal tube tip to facilitate insertion through the percutaneously dilated stoma site. The tracheostomy tube has a neck flange, an integral 15 mm connector, and a cuff which deflates to a low profile on the tube for a smooth transition during insertion. The cuff inflation line has a self sealing Luer valve. The tracheostomy tube is supplied with a disposable inner cannula of the appropriate size. The Percutaneous Tracheostomy Kit comes with the necessary components for percutaneous tracheostomy tube insertion into a stoma created by serial dilation.

INDICATIONS FOR USE

The PER-FIT™ Percutaneous Dilational Tracheostomy Kit with Specialty Tracheostomy Tube and Disposable Inner Cannula is indicated for use in providing percutaneous temporary tracheal access for airway management.

TECHNICAL CHARACTERISTICS

The PER-FIT™ Percutaneous Dilational Tracheostomy Kit with Specialty Tracheostomy Tube and Disposable Inner Cannula has the same technical characteristics as is currently marketed with our existing PER-FIT™ Percutaneous Dilational Tracheostomy Kit with Specialty Tracheostomy Tube and Disposable Inner Cannula, K980466[K960429]. The device is being modified to increase the bevel angle and change to the anterior position, slightly modify the shape of the tube and inner cannula [increased arc of curvature, reduced length of straight portion resulting in an overall decrease in nominal length], provide an angled obturator/introducer, and add marking on the dilator stop on the guiding catheter. The Instructions for Use Physician's Clinical Guide are also revised to reflect these changes.

SUMMARY OF NONCLINICAL AND CLINICAL TESTS

A side-by-side comparison of the proposed device to three legally marketed devices has been conducted, covering intended use, materials and design characteristics. A clinical user evaluation has been conducted at St. John's Mercy Medical Center with 28 subjects in the control group and 26 subjects in the two study groups.

CONCLUSION OF NONCLINICAL AND CLINICAL TESTS

The side-by-side comparison concluded that the proposed device is substantially equivalent to the predicate devices cited.

The clinical user evaluation concluded that the reduction in the incidence of occlusion of the tracheostomy tube with the proposed device was statistically highly significant. It was concluded that the proposed device is at least equivalent to the current device in these respects.

The evaluation also found that there was no trauma or difficulty associated with insertion of the tube featuring the modified bevel and using the angled obturator. This provided useful support of the conclusion that the proposed device is equivalent to the predicate device(s) in these respects.

CONCLUSION

The proposed device is safe and effective and is substantially equivalent to the predicate devices.

Portex, Inc.

Timothy J. Talcott
Director, Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2003

Mr. Timothy J. Talcott
Portex, Incorporated
10 Bowman Drive
Keene, New Hampshire 03431

Re: K031057
Trade/Device Name: PER-FIT™ Percutaneous Dilational Tracheostomy Kit with Specialty Tracheostomy Tube and Disposable Inner Cannula
Regulation Number: 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: JOH
Dated: April 2, 2003
Received: April 3, 2003

Dear Mr. Talcott:

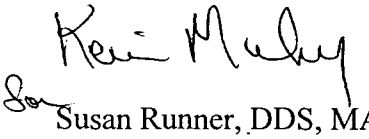
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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/tray. 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) 594-4646. 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

B: INTENDED USE OF DEVICE

510(k) Number (if known): K031057

Device Name: PER-FIT™ Percutaneous Dilational Tracheostomy Kit with Specialty Tracheostomy Tube and Disposable Inner Cannula

Indications For Use:

The PER-FIT™ Percutaneous Dilational Tracheostomy Kit with Specialty Tracheostomy Tube and Disposable Inner Cannula is indicated for use in providing percutaneous temporary tracheal access for airway management.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

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

510(k) Number: K031057