MAY 26 2005 K050166

Portex Emergency Cricothyroidotomy Kit 510(k) Notification

Section 7: Summary of Safety and Effectiveness (k)510 Summary

510k SUMMARY:

COMPANY INFORMATION:

Smiths Medical International,
Hythe, Kent.
England CT21 6DB

CONTACT: Barry Smith
Regulatory Affairs Manager

PREPARATION DATE OF SUMMARY:
21/01/2005

TRADE NAME
Portex Emergency Cricothyroidotomy Kit

COMMON NAME
Emergency Airway Needle

PRODUCT CLASS/CLASSIFICATION
Class II 73, 21 CFR 868.5090

PREDICATE DEVICES

Cook Melker Emergency Cricothyroidotomy Sets.	(k)013916 & (k)010016
Portex Blue Line Ultra Tracheostomy Tube	(k)030381
Portex Blue Line Directional Tracheal Tube	(k)931735
Portex Per-fit Percutaneous Tracheostomy Kit	(k)031057
Mectra Labs Pneumoperitoneum Insufflation Needle	(k)021247
Portex Steri-Cath	(k)923559

DESCRIPTION:
The new cricothyroidotomy kit is designed for introduction of an emergency 6mm cuffed airway tube through the cricothyroid membrane. The airway tube is provided pre-assembled onto a dilator with a Veress needle located in the centre.

The kit employs two well-established and understood techniques:
Firstly: The use of a Veress needle to provide visual indication of entry into a body cavity. (the trachea). (This can be confirmed by aspiration through the needle as with the predicate Cook Melker product ref. IFU in Attachment B(i)) The Veress needle is usually used for insufflation of the abdomen. It has a central sprung-loaded protective core to the needle that guards the cutting point and gives a visual indication via a "flag" at the hub end of the needle when the needle tip is

passing through tissues. When the needle tip passes through into the abdominal cavity, or trachea, the protective core springs forward to guard the needle tip and the "flag" drops down out of sight.

Secondly: the use of a dilator/introducer to enlarge a stomal opening and place an airway tube within the trachea. The pre-assembled needle/dilator/tube is inserted through the cricothyroid membrane together and the tube is then slid off the dilator fully into the trachea. This is the same principle employed by the Cook Melker Cricothyroidotomy set.

As well as the airway tube assembly, the kit provides the user with scalpel for skin incision, syringe for aspiration to confirm location of the needle in the trachea, sutures and neck-strap to secure the airway tube and a heat and moisture exchanger to reduce patient energy loss and protect the airway from blockage. These are all items that will be well understood by the user.

Packaging comprises a rigid hinged blister pack for protection and a polythene/Tyvek welded pouch as the sterile barrier.
Each pack is EO sterilised and individually packed in a carton together with the directions for use.

INDICATIONS FOR USE:

Emergency airway access (when endotracheal intubation is not possible) by percutaneous insertion of a cricothyroidotomy tube through the cricothyroid membrane.

TECHNICAL CHARACTERISTICS:

The Portex Emergency Cricothyroidotomy Kit comprises of components and materials that have predicates in similar medical devices currently being legally marketed in the USA.

CONCLUSION

The data provided and comparison to the predicate devices demonstrate that the proposed device is safe and effective and substantially equivalent to the predicate device/s.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 26 2005

Mr. Christopher Turnbull
Senior Development Manager
Smiths Medical International
Hythe, Kent
ENGLAND CT21 6DB

Re: K050166
Trade/Device Name: Portex Emergency Cricothyroidotomy Kit
Regulation Number: 21 CFR 868.5090
Regulation Name: Emergency Airway Needle
Regulatory Class: II
Product Code: BWC
Dated: April 12, 2005
Received: April 15, 2005

Dear Mr. Turnbull:

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.

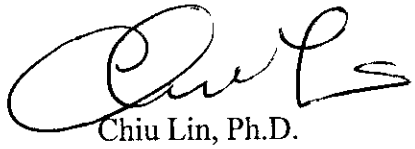
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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/industry/support/index.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

ATTACHMENT 12

Indications for Use

510(k) Number (if known): 050166

Device Name: Portex Emergency Cricothyroidotomy Kit

Indications For Use:

Emergency airway access (when endotracheal intubation is not possible) by percutaneous insertion of a cricothyroidotomy tube through the cricothyroid membrane.

Prescription Use Yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 801 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 K050166