K083031

SECTION 5:
510(k) SUMMARY

AUG 1 8 2009

Trade Name: Portex® UniPerc™ Percutaneous Dilation Tracheostomy Kit

Common Name: Percutaneous Tracheostomy Kit

Classification Name: Tracheostomy tube and tube cuff (21 CFR 888.5800, Product Code JOH)

Contact Person:
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Equivalent to:
Portex® Percutaneous Dilation Tracheostomy Kit with Serial Dilators (K040014)
Portex® Percutaneous (GWDF) Tracheostomy Kit (K060945)
Portex® UltraPerc Tracheostomy kits (K041348)
Smiths Point-Lok Device (K946289)
Portex® Blue Line Ultra Tracheostomy tubes (K030381)
Portex® Adjustable Flange Tracheostomy Tube (K962175)
Portex® Reinforced Tracheal Tubes Cuffed and Uncuffed (K032112)
Kapitex Inner Cannula Cleaning Swabs (Class 1 exempt)

Device Description: The UniPerc™ device has been designed to facilitate percutaneous tracheostomy in patients with a large neck mass and a consequently large skin to anterior trachea depth. The UniPerc™ device is centered on an extra length, wire reinforced, pre-curved, cuffed or uncuffed, tracheostomy tube mounted with an adjustable flange. The tube is supplied with an inner cannula, which can be used to line the internal surface of the tube. Obturators, dilators and other parts are supplied with the various kits.

The UniPerc™ device is designed for insertion using existing, dilating percutaneous or surgical insertion techniques. Care of the device whilst in use also follows existing standards techniques.

Intended Use: 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, fibreoptic bronchoscopy, breathing and circulation, and one to perform the procedure.

The graduated single stage dilator has a lubricious hydrophilic coating when wetted, to improve its ease of insertion.

Substantial Equivalence:

The Portex® UniPerc™ Percutaneous Dilation Tracheostomy Kit has the same intended use as the Portex UltraPerc Tracheostomy Kits.

The Portex® UniPerc™ Percutaneous Dilation Tracheostomy Kit is composed essentially of the same materials as the predicate Portex Limited kits and tubes listed in the predicate device section. The Portex® UniPerc™ Percutaneous Dilation Tracheostomy Kit incorporates a number of design and performance characteristics from the Portex® UltraPerc™ Tracheostomy Kits, the Portex® Percutaneous Tracheostomy Tube kits and the Portex® Adjustable Flange Tracheostomy Tube, including similar sterilization and packaging processes.

The determination of substantial equivalence of the Portex® UniPerc™ Percutaneous Dilation Tracheostomy Kit to the predicate devices was based on a comparison of device technological characteristics, intended use and materials of composition.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Smiths Medical ASD, Incorporated
C/O Mr. John Tullet
Regulatory Affairs Manager
Smiths Medical International, Limited
Boundary Road
Hythe, Kent
UNITED KINGDOM CT216JN

AUG 1 8 2009

Re: K083031
Trade/Device Name: Portex® UniPerc™ Percutaneous Dilation Tracheostomy Kit
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: BTO
Dated: August 7, 2009
Received: August 14, 2009

Dear Mr. Tullett:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4:
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K083031

Device Name: Portex® UniPerc™ Percutaneous Dilation Tracheostomy Kit.

Indication For Use: Portex ® UniPerc™ single use Percutaneous Dilation Tracheostomy (PDT) Kits allows the controlled, elective subcricoid percutaneous insertion of an adjustable flange tracheostomy tube for airway management using a Seldinger guidewire dilation technique in patients with a large neck anatomy (up to a maximum of 50mm of pre-tracheal soft tissue anterior to the trachea) where standard length flange tracheostomy tubes are too short.

Tracheostomy tube maximum period of use 29 days.

L Schutte

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

510(k) Number: K083031

Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/ OR

Over-The-Counter Use _____
(Per 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)