APR 23 2010

5. 510(k) Summary

Cook Incorporated
VersaTube™ Tapered Tracheostomy Tube with Disposable Inner Cannula
510(k) Summary
21 CFR 807.92

1. Submitter Information:

Applicant:	Cook Incorporated
Address:	750 Daniels Way P.O. Box 489 Bloomington, IN 47402
Phone Number:	(800) 468-1379
Fax Number:	(812) 332-0281
Contact:	Susanne Galin, RAC
Contact Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	812-339-2235 x2296
Contact Fax Number:	812-332-0281

2. Device Information:

Trade name:	VersaTube™ Tapered Tracheostomy Tube with Disposable Inner Cannula
Common name:	Tube Tracheostomy and Tube Cuff
Classification:	Class II
Regulation:	21 CFR § 868.5800 Tracheostomy tube and tube cuff
Product Code:	BTO

3. Predicate Devices:

Cook Incorporated's VersaTube™ Tapered Tracheostomy Tube with Disposable Cannula (hereafter referred to as the VersaTube) is substantially equivalent to the Portex® Blue Line Ultra® Tracheostomy Tube originally manufactured by Portex Ltd. under 510(k) clearance K030381.

4. Device Description:

The VersaTube is a sterile, single use cuffed tracheostomy tube with a disposable inner cannula, and will be manufactured as a 7, 8, or 9 mm ID device (with the inner cannula being either 6, 7, or 8 mm ID). The angle of curvature of the VersaTube is 96° (7, 8 mm ID) or 97 ° (9 mm ID) and ranges from 78 to 98 mm. The neck-plate, 15 mm airway connector, and inner cannula are color coded to marry together the tracheostomy tube with the correctly sized inner cannula. The device is not intended to be used for more than 29 days.

5. Intended Use:

The VersaTube Tapered Tracheostomy Tube is intended to provide an artificial airway to establish airway patency and to provide maintenance of the airway.

6. Technological Characteristics:

The VersaTube consists of a polyvinyl chloride outer cannula which is tapered at the distal end for smooth insertion. The device also incorporates a low pressure, high volume balloon cuff at the distal end of the device for the purpose of sealing the airway for proper ventilation. Included with the VersaTube are two inner cannulae. Each inner cannula is designed for a close fit to the corresponding size VersaTube.

The technological characteristics of the VersaTube and the predicate device, the Portex Blue Line Ultra Tracheostomy Tube, are substantially equivalent in that both devices have the same main trachestomy tube materials, components, basic design, and function. No new technological aspects are being introduced with the proposed device.

To demonstrate reliable design and performance of the VersaTube, the following verification testing was performed:

- Strength of neck-plate and 15 mm connector attachment to cannula,
- Cuff performance,
- Insertion force,
- Inner cannula extraction force,
- Sterilization testing,
- Biocompatibility testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Susanne Galin
Regulatory Affairs Specialist
Cook, Incorporated
750 Daniels Way
P.O. Box 489
Bloomington, Indiana 47402

APR 23 2010

Re: K100283
Trade/Device Name: VersaTube™ Tapered Tracheostomy Tube with Disposable Inner Cannula
Regulation Number: 21 CFR 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: BTO
Dated: January 29, 2010
Received: February 1, 2010

Dear Ms. Galin:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K100283

Device Name: VersaTube™ Tapered Tracheostomy Tube with Disposable Inner Cannula

Indications for Use:

The VersaTube™ Tapered Tracheostomy Tube is intended to provide an artificial airway to establish airway patency and to provide maintenance of the airway.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

)ivision Sign-Off)
)ivision of Anesthesiology, General Hospital
.nection Control, Dental Devices

10(k) Number: K100283