K082520

OCT 02 2008

Special 510(k) Summary

1. **Company Identification**

   Covidien, (formerly Nellcor Puritan Bennett, Inc.)
   6135 Gunbarrel Avenue
   Boulder, CO 80301

   Establishment Registration: 2936999

2. **Contact Person**

   Scott Dickerhoff
   Director, Regulatory Affairs
   Phone: (303) 305-2382
   Fax: (303) 305-2212
   Email: scott.dickerhoff@covidien.com

3. **510(k) Preparation Date**

   July 15, 2008

4. **Device Name**

   Trade Name: SealGuard Endotracheal Tube and SealGuard Evac Endotracheal Tubes.
   Common Name: Endotracheal Tube, Tracheal Tube

5. **Device Classification**

   Class II per 21 CFR 878.5730

6. **Indications for Use**

   The SealGuard Evac Endotracheal tube is indicated for airway management by oral/nasal intubation of the trachea, and for evacuation or drainage of the subglottic space.

   The SealGuard Endotracheal tube is a device inserted into a patient's trachea via the nose or mouth to maintain an open airway.

7. Description of Device

SealGuard™ Endotracheal Tube (5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 10mm)

SealGuard™ Evac Endotracheal Tube - Oral (6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0mm)

The SealGuard™ and the SealGuard™ Oral Evac Tracheal Tubes are sterile, single-use devices supplied with a standard 15mm connector. On the Evac tubes, in addition to the main lumen, the tube has a separate Evac lumen which has a dorsal opening above the cuff. Access to the lumen is accomplished via a clear connecting tube with a capped Luer connector. The tube features a unique ultra thin high volume low pressure cuff and self sealing valve with attached pilot balloon. The unique cuff material of the SealGuard products ideally gives an improved sealing performance over historical PVC cuffed product. The tube incorporates a Magill curve, a hooded tip with Murphy Eye and a Tip-To-Tip™ radiopaque line to assist in radiographic visualization.

8. Substantial Equivalence

The predicate devices to which we claim equivalence are the Hi-Lo Cuffed Tracheal Tube (K871204), and the Hi-Lo Evac Endotracheal Tubes (K965132).

The SealGuard Endotracheal tube and the SealGuard EVAC Endotracheal tubes maintain the same intended use as the predicate device. It is a device inserted into the trachea through the mouth or nose to facilitate breathing.

The SealGuard Endotracheal tube & SealGuard EVAC Endotracheal tubes and the predicate device consist of the same fundamental technology.

The SealGuard Endotracheal tube and the SealGuard EVAC Endotracheal tubes differ from the predicate device in that the cuff material is PU (polyurethane) and the predicate device cuff is PVC (polyvinylchloride). In addition, the shape of the cuff is modified from a barrel shape to a tapered shape.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 02 2008

Mallinckrodt Medical
C/O Mr. Scott Dickerhoff
Director, Regulatory Affairs
Covidien
6135 Gunbarrel Avenue
Boulder, Colorado 80301

Re: K082520
Trade/Device Name: SealGuard Tracheal Tubes and SealGuard Evac Tracheal Tubes
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: August 29, 2008
Received: September 2, 2008

Dear Mr. Dickerhoff:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Samuel Gerdts for //

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

Indications for Use

510(k) Number: _____

Device Name: SealGuard Tracheal Tubes and SealGuard Evac Tracheal Tubes

Indications for Use:

The SealGuard Evac Endotracheal tube is indicated for airway management by oral/nasal intubation of the trachea, and for evacuation or drainage of the subglottic space.

The SealGuard Endotracheal tube is a device inserted into a patient's trachea via the nose or mouth to maintain an open airway.

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

510(k) Number: K080620

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