Hospitech Respiration

MAR - 2 2010

510(K) SUMMARY

AnapnoGuard™ Endotracheal Tube

510(k) Number K 093126

Applicant's Name: **Hospitech Respiration Ltd.**
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Preparation Date: September 21, 2009

Trade Name: ***AnapnoGuard™ ETT***

Device Type **Tracheal Tube**

Classification: **Regulatory Name:** tube, tracheal

Product Code: BTR

Regulation No: 21 CFR 868.5730

Class: II

Classification Panel: Anesthesiology

Device Description:

The ***AnapnoGuard™ Endotracheal Tube*** is a sterile, single-use device supplied with main lumen with a standard 15mm connector. Four lumens are embedded within tube walls. One is a standard lumen used for the inflation/deflation of the cuff. Two suction lumens are embedded in the dorsal side of the tube having spatially divided inlet ports above the cuff. The two suction lumens are unified into one external lumen. These lumens are used to evacuate secretions that accumulate above the cuff.

A forth lumen is embedded on the ventral side of the tube having an inlet port above the cuff. It is used for a) venting the subglottis space during suction to avoid vacuum b) for saline (or other fluid) rinsing above the cuff to dilute the secretions and ease the suction c) for air sampling above the cuff to detect leakage of air from the lungs past the cuff.

The AnapnoGuard ETT is comprised of the following components:

- Main lumen (PVC or Silicone)
- Cuff (Polyurethane for PVC tube and Silicone for Silicon tube)
- Cuff inflate/deflate lumen
- Two suction lumens combined into one outside of the tube sealed with a cap
- Venting/air and CO2 sampling lumen sealed with a cap.
- Murphy eye (with or without)

Intended Use Statement:

The ***AnapnoGuard™ Endotracheal Tube*** is indicated for airway management by oral or nasal intubation of the trachea and for evacuation or drainage of the subglottic space.

Predicate Devices: Substantial equivalence to the following predicate devices is claimed:

Device Name	Manufacturer	510k No	Date of approval
SealGuard Endotracheal Tube	Covidien	k082520	Oct 2, 2008
Well Lead Endotracheal tube	Well Lead	k042683	Feb 18, 2005

Performance Standards

AnapnoGuard™ Endotracheal Tube was tested and complies with the following standards:

- ISO 5361:1999 Anaesthetic and respiratory equipment -- Tracheal tubes and connectors
- *ANSI/AAMI/ISO 11135*-1:2007 Sterilization of health care products — Ethylene oxide

- AAMI TIR28:2001 Product adoption and process equivalency for ethylene oxide sterilization
- ISO 14971-1:2007 Risk management for medical devices
- ISO 10993-1:2003(E), Biological evaluation of medical devices -- Part 1: Evaluation and testing

A detailed description appears in **Section 14**.

Bench Tests

Bench testing demonstrated that the ***AnapnoGuard™ Endotracheal Tube*** is as safe and effective as the cleared predicate devices.
The following bench tests were conducted:

- Determination of Cuff Resting Diameter
- Resistance to Cuff Herniation
- Cuff Symmetry
- Suction Safety Test
- Resistance to tube collapse

Summary of Pre-Clinical and clinical study

Preclinical study was designed in order to evaluate the safety and effectiveness of using the ***AnapnoGuard ETT*** device as an endotracheal tube intended for airway management by oral or nasal intubation. Altogether 6 goats were intubated for 4 to 6 hours. No occlusion or any adverse events occurred during the study, airway stay open throughout study procedure. Study has demonstrated that the ***AnapnoGuard ETT*** device is safe and effective for its intended use (pre-clinical study summary is provided in attachment No. 10).

Due to the pre-clinical study performed with the ***AnapnoGuard ETT*** device, the thorough performance tests and comprehensive clinical study performed by the cleared predicate device (Attachment No. 9), Hospitech believes that clinical studies are not required to determine the safety and efficacy of the device.

Comparison to the Predicate Device

The ***AnapnoGuard™ Endotracheal Tube*** has the same intended use, general and specific indications and principles of operation as the cleared Covidien's SealGuard Endotracheal Tube (K082520).
The material composition of both is the same; the lumens are made of PVC and the cuff of PU (polyurethane).

The minor differences between the AnapnoGuard and the SealGuard Endotracheal Tube do not raise any new questions of safety or efficacy. Moreover, bench and preclinical testing of the ***AnapnoGuard™ Endotracheal Tube*** (bench testing are provided in Attachments 7) demonstrated that the ***AnapnoGuard™ Endotracheal Tube*** is as safe and effective as the predicate devices. Thus, the ***AnapnoGuard™ Endotracheal Tube*** is substantially equivalent to the already cleared SealGuard Evac Endotracheal Tube.

The PVC of the ***AnapnoGuard™ Endotracheal Tube*** PVC model is identical to the PVC of the Well Lead Endotracheal Tube cleared in K042683 and the Silicone of the ***AnapnoGuard™ Endotracheal Tube*** Silicone model is identical to the silicone of the All-Silicone 2-Way and 3-Way Hematuria Catheter cleared in K021142

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

MAR 11 2010

Mr. Yoram Levy
Regulatory Consultant
Hospitech Respiration Limited
20 Hamagshimim Street
Kiryat Matalon
Petach Tikva 49348
ISRAEL

Re: K093126
Trade/Device Name: AnapnoGuard Endotracheal Tube
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: February 14, 2010
Received: March 2, 2010

Dear Mr. Levy:

This letter corrects our substantially equivalent letter of March 2, 2010 .

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 (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/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

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

Enclosure

Hospitech Respiration

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: *AnapnoGuard™ Endotracheal Tube*

Indications for Use: The *AnapnoGuard™ Endotracheal Tube* is indicated for airway management by oral or nasal intubation of the trachea and for evacuation or drainage of the subglottic space.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of Anesthesiology,
510(k) Number

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

510(k) Number: K093126