DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 16, 2016

Hospitech Respiration Ltd
c/o Yoram Levy
Qsite General Manager
Qsite
31 Haavoda St.
Binyamina 30500
Israel

Re: K150157
Trade/Device Name: AnapnoGuard 100 Respiratory Guard System
Regulation Number: 21 CFR 868.5750
Regulation Name: Inflatable Tracheal Tube Cuff
Regulatory Class: Class II
Product Code: BSK, BTR
Dated: December 19, 2015
Received: December 28, 2015

Dear Mr. Levy,

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

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Clinical Deputy Director
DAGRID/ODE/CDRH FOR

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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150157

Device Name
AnapnoGuard 100 Respiratory Guard System

Indications for Use *(Describe)*
AnapnoGuard 100 Respiratory Guard System is intended for airway management by oral/nasal intubation while providing continuous endotracheal cuff pressure control using non-invasive measurement and monitoring of carbon dioxide concentration in the subglottic space and evacuation of secretions from above the endotracheal tube's cuff.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(K) SUMMARY

AnapnoGuard 100 Respiratory Guard System

510(k) Number K150157

Applicant's Name: Hospitech Respiration Ltd
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Yoram@qsitemed.com

Trade Name: ***AnapnoGuard 100 Respiratory Guard System***

Summary Preparation Date: **January 15, 2015**

Classification:

Classification name: Cuff, tracheal tube, inflatable
Product Code: BSK
Regulation No: 21 CFR 868.5750
Class: II
Panel: Anesthesiology

Device Description:

AnapnoGuard 100 Respiratory Guard System is comprised of the following three main components:

- The AnapnoGuard endotracheal tube (ETT) with inflatable cuff (FDA cleared under K093126).
- The ***AnapnoGuard 100 Respiratory Guard System*** interconnection harness of tubes, connecting the ETT to the AnapnoGuard 100 control unit
- The ***AnapnoGuard 100 Respiratory Guard System*** control unit which consists of the following main modules:
- **Host computer (PC)**
- **Microcontroller (MCU)**

- **Suction module** (regulator and flow potency meter): including a set of valves and pipes controlling the secretions suction/evacuation from above the ETT cuff.
- **Rinsing module**: Pumps saline to rinse the Suction and Vent/ CO_2 lumens.
- **CO_2 analyzer module:** including CO_2 analyzer assembly, pump, valve and flow filter which sucks air from the subglottic space above the ETT cuff into the CO_2 analyzer.
- **Cuff pressure module:** includes two pressure gauges which monitor cuff pressure, a miniature air pump and two valves.
- **Pneumatic module:** valves, pipes and filters
- **Connectors panel** for connecting the interconnection harness (ETT), vacuum, trap bottle, rinsing fluid and filters.
- **Operation buttons panel and navigation wheel**
- **I/O communication panel**
- **Display monitor**

AnapnoGuard 100 Respiratory Guard System, including its three components monitors leak between the endotracheal tube's cuff and the trachea by measuring the Carbon Dioxide levels in the subglottic area above the cuff through a dedicated lumen in the endotracheal tube. Detection of a high level of Carbon Dioxide is an objective indicator for a leak (improper sealing of the trachea by the endotracheal tube cuff). The system continuously monitors and adjusts the cuff pressure to prevent a leak at minimum possible pressure (all within pressure limits preset by the user).

Preventing a leak reduces the likelihood of aspiration of secretions from the upper airways into the lungs and increases the likelihood for no loss of ventilation and delivery of anesthetic and nebulized drugs into the lungs. Keeping the cuff pressure as low as possible reduces the mechanical pressure of the cuff on the tracheal tissue throughout the intubation period.

The system also performs evacuation of secretions from above the endotracheal tube's cuff through a dedicated lumen at the dorsal side of the endotracheal tube.

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Indication for Use:

AnapnoGuard 100 Respiratory Guard System is intended for airway management by oral/nasal intubation while providing continuous endotracheal cuff pressure control using non-invasive measurement and monitoring of carbon dioxide concentration in the subglottic space and evacuation of secretions from above the endotracheal tube's cuff.

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

Device Name	**510k No**	**Clearance Date**
PYTON *Cuff Pressure Regulator*	K092733	Feb 26, 2010
SIMEX subglottic Aspiration System (suction)	K141255	September 22, 2014
Hospitech Respiration *AnapnoGuard Endotracheal Tube* (ETT)	K093126	March 2, 2010

Reference devices:

Device Name	**510k No**	**Clearance Date**
Covidien *SealGuard™ Evac*	K082520	October 2, 2008
TELEFLEX ISIS™	K091761	October 29, 2009
Mallinckrodt Ty-Care Closed Suction System	K031997	November 25, 2003
SUNMED *CuffAlert™*	K081805	Nov 14, 2008
Ohio Push-To-Set Intermittent and Continuous Vacuum Regulators	class II Product Code KDP Regulation No. 21CFR 880.6740	
NS Series *Vacuum/Pressure Gauges*	K081778	Sep 12, 2008
MicroCap Plus/NPB-75	K024300	Apr 03, 2003
Hamilton Cuff Pressure Regulator (IntelliCuff)	K103803	Nov 3 , 2011
Boehringer Laboratories CASS Regulator Model 3720	class II Product Code KDP Regulation No. 21CFR 880.6740	

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Comparison with PYTON Pressure Regulator predicate device

Characteristic	*AnapnoGuard 100 Respiratory Guard System (Submitted)*	*PYTON Cuff Pressure Regulator (K092733)*
Intended use	***AnapnoGuard 100 Respiratory Guard System*** is intended for airway management by oral/nasal intubation while providing continuous endotracheal cuff pressure control using non-invasive measurement and monitoring of carbon dioxide concentration in the subglottic space and evacuation of secretions from above the endotracheal tube's cuff.	To measure and regulate intra-cuff pressures of endotracheal supraglottic airways or tracheostomy tubes. The PYTON is intended for use on patients who are intubated.
Regulatory Class	II	II
Product Code, Regulation Number	BSK 21 CFR 868.5750	BSK 21 CFR 868.5750
Minimum measured pressure	0 mmHg	15 mmHg 20 Cm H_2O
Maximal cuff pressure	33 mmHg (47 cmH2O)	22 mmHg 30 Cm H_2O
Control Accuracy	±0.1 mmHg (0.13 cmH2O)	±0.73 mmHg (±1 cmH2O)
Recording Accuracy	±0.1 mmHg (0.13 cmH2O)	±0.73 mmHg (±1 cmH2O)
Pressure drop Alarm time	0.2 Sec	NA
Pressure rise alarm time	0.2 Sec	NA
Power Supply	110 – 220 V with backup battery	110 – 220 V with backup battery

Comparison for the SIMEX subglottic suction predicate device

	AnapnoGuard 100 Respiratory Guard System (Submitted)	**K141255 SIMEX subglottic Aspiration System**
Manufacturer	Hospitech Respiration Ltd.	SIMEX Medizintechnik, GmbH
Intended use	***AnapnoGuard 100 Respiratory Guard System*** is intended for airway management by oral/nasal intubation while providing continuous	The SIMEX subglottic Aspiration System models cuff M and cuff S are indicated for vacuum suction, extraction,

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	AnapnoGuard 100 Respiratory Guard System (Submitted)	**K141255 SIMEX subglottic Aspiration System**
	endotracheal cuff pressure control using non-invasive measurement and monitoring of carbon dioxide concentration in the subglottic space and evacuation of secretions from above the endotracheal tube's cuff.	aspiration and removal of surgical fluids, tissue (including bone), bodily fluids or infectious materials from wounds or from patient's airway or respiratory system, either during surgery or at patient's bed side.
Product Code, Regulation Number	BSK 21 CFR 868.5750	BTA 21 CFR 878.4780
Regulatory Class	II	II
Suction Pressure Range	-20 up to -120 mmHg	-15 to -225 mmHg (-20 to -300 mbar)
Mode of operation	Manual Intermittent	Manual Intermittent:
Closed System	Yes	Yes
Indications for single patient use	No	No
Allows ETT replacement without disconnecting patient from ventilator	Yes	Yes
Manual control of vacuum	Yes	Yes
Patient Population	Adults	Adults and pediatric
Evacuation of secretions from above the endotracheal tube's cuff	yes	Yes
Biocompatibility	All materials that come in contact with the patient body or liquids are	Same

	AnapnoGuard 100 Respiratory Guard System (Submitted)	**K141255 SIMEX subglottic Aspiration System**
	biocompatible and compliant with ISO 10993-1	
Flow Rate	0 to 15 L/min	8 L/Min

Comparison for the AnapnoGuard ETT

Characteristics	**Proposed AnapnoGuard 100 Respiratory Guard System**	**Hospitech Respiration AnapnoGuard Endotracheal Tube (ETT) (K093126)**
Intended use	***AnapnoGuard 100 Respiratory Guard System*** is intended for airway management by oral/nasal intubation while providing continuous endotracheal cuff pressure control using non-invasive measurement and monitoring of carbon dioxide concentration in the subglottic space and evacuation of secretions from above the endotracheal tube's cuff.	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.
Product Code	BSK	BTR
Regulation No.	21 CFR 868.5750	21 CFR 868.5730
Classification	Class II	Class II
Supplied/use	Disposable (ETT portion)	Disposable
Prescription use/OTC use	Prescription use	Prescription use
Environment of use	Hospitals, Intensive Care Units, Mobile Intensive Care units and Clinics.	Same
Intended users	Health care professionals	Same
Intended population	All ages, up to the appropriate ETT size	Same
Biocompatibility	All materials are biocompatible and compliant with ISO 10993-1	Same
Sterilization method	ETO	ETO
Performance Standards	ISO 5361	Same

Characteristics	Proposed AnapnoGuard 100 Respiratory Guard System	Hospitech Respiration AnapnoGuard Endotracheal Tube (ETT) (K093126)
Sizes (Input Diameter) [mm]	6.5, 7.0, 7.5, 8.0, 8.5, 9.0 mm	Same
Murphy's Eye	With or without	Same
Number of lumens (except main lumen)	4 of which 2 are combined into one suction lumen: 1: suction x 2 2: Vent, rinsing, air sampling 3: Cuff inflation /deflation	Same
Suction lumens	Two suction lumens combined into one at the proximal end, outside the tube wall	Same
Tracheal tube maximum period	29 days	29 days
Reusable or disposable	Disposable	Disposable
Storage Environment	Ambient Temperature: -20º C to 40ºC (-4°F to 104°F) Pressure: 430 mmHg to 795 mmHg	Same
Operating environment	Ambient temperature: 0÷50^{o}C (32°F - 122°F) Humidity: 10÷80% non condensing Altitude: -1,250 feet to 15,000 feet	Same

The ***AnapnoGuard 100 Respiratory Guard System*** primary predicate device is the PYTON *Cuff Pressure Regulator* (K092733) for its cuff pressure control. It has similar intended use and technology as the cuff pressure control of the ***AnapnoGuard 100 Respiratory Guard System*** section. The ***AnapnoGuard 100***'s limits of presetting the target cuff pressure range are within the PYTON Cuff Pressure Regulator predicate device limits.

The ***AnapnoGuard 100*** ETT is the same ETT that was cleared as Hospitech's AnapnoGuard Endotracheal Tube (ETT) K093126.

The Hospitech ***AnapnoGuard 100 Respiratory Guard System*** Cuff Pressure Monitor is as safe and as effective as the PYTON Cuff Pressure Regulator (K092733) and referenced to the Hamilton Cuff Pressure Regulator (IntelliCuff) (K103803. The ***AnapnoGuard 100 Respiratory Guard System*** cuff pressure unit has similar intended use and technological characteristics and is within the cuff pressure of these devices.

The ***AnapnoGuard 100 Respiratory Guard System*** suction unit is as safe and as effective as the K141255 SIMEX subglottic Aspiration System. The K141255 SIMEX subglottic Aspiration System predicate devices, has similar intended use and technology and is as safe and as effective as the ***AnapnoGuard 100 Respiratory Guard System*** regarding the suction power and the cyclical and automatic suctioning and it can define the length and the interval of the suction as it is done by the AnapnoGuard 100 Respiratory Guard System.

The vacuum pressure of the ***AnapnoGuard 100 Respiratory Guard System*** is within the vacuum pressure parameters of its predicate device.

Performance Standards:

AnapnoGuard 100 Respiratory Guard System complies with the following voluntary standards:

- IEC 60601-1:2005/EN 60601-1:2006 Medical Electrical Equipment – Part 1, General requirements for basic safety and essential performance 3rd Edition
- IEC 60601-1-2:2007 (Electromagnetic compatibility (EMC)
- ISO 5361:2012 (Anesthetic and Respiratory Equipment – Tracheal Tubes and Connectors)
- EN ISO 10993-1:2003 Biological Evaluation of Medical Devices
- ISO 14971:2007 Risk management for medical devices
- 60601-1-10:2014 General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for

the Development of Physiologic Closed-Loop Controllers. (General II (ES/EMC))

Performance Bench Tests

The following bench performance testing was performed:

Name of test	Purpose
ETT: Determination of Cuff Resting Diameter	Measure the cuff resting diameter.
ETT: Resistance to Tube Collapse	Validate that the tube doesn't cave in from inward cuff pressure
ETT: Resistance to Cuff Herniation	Validate that the cuff does not herniate the tube's airway.
ETT: Cuff Symmetry	Validate the symmetry of the cuff.
Suction Module: Suction Safety Test	Evaluate that the suction is safe.
Suction Module: Determination of AnapnoGuard suction capacity	Validate the ability of the AnapnoGuard 100 system to perform suction of the secretions according to the viscosity and rate of secretion production of the average patient.
Cuff pressure: Cuff Pressure Safety Test	Validate the AnapnoGuard 100 design in maintaining cuff pressures precision and safety boundaries
CO2 Analyzer: CO_2 Sensor Precision Test	Test the CO_2 Sensor Precision.
Cuff Pressure: Pressure Maintenance Comparison (Tracoe)	Compare the ability of the AG 100 to maintain constant pressure in comparison to the existing Tracoe Pressure Regulator
System: Integrated Performance Test	Test the performance of the system when operating in full spectrum using a patient simulator.
Physiological closed loop	Evaluate the physiological closed loop between the CO2 measurements and the suction control. This was done by bench testing and theoretical study in conformance to applicable clauses of 60601-1-10

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Bench testing demonstrated that the ***AnapnoGuard 100 Respiratory Guard System*** is as safe and as efficient for performing its intended use.

Preclinical Performance Data

The safety and feasibility of the ***AnapnoGuard 100 Respiratory Guard System*** were not evaluated by pre-clinical study.

Human factors/usability studies

A total of 45 professional team participants, the target population for operating the ***AnapnoGuard 100 Respiratory Guard System***, were enrolled in the study.

The results of this usability study clearly indicate that User Manual and the Graphic Use Interface (GUI) of the ***AnapnoGuard 100 Respiratory Guard System*** are clear. The usability study demonstrated the safety and effectiveness use of the device, when operated by intended user's hospital professional team.

Summary of Clinical Performance Data:

Background

The clinical performance of the ***AnapnoGuard 100 Respiratory Guard System*** as airway management tool in mechanically ventilated patients was evaluated in prospective, two arms controlled and multi-center study.

Methods

The study included intensive care and post-operative patients expected to be mechanically ventilated for at least 12 hours. Following screening and enrollment, patients were randomized to study or control group.

Study group patients were intubated with the AnapnoGuard ETT and connected to the control unit of the ***AnapnoGuard 100 Respiratory Guard System*** operating in its full clinical mode, where the subglottic secretions suction and cuff pressure control was enabled (ON mode).

Control group patients were treated according to the current standard of care- patients were intubated with the AnapnoGuard ETT and connected to the control unit of the ***AnapnoGuard 100 Respiratory Guard System*** where the subglottic secretions suction was enabled but cuff pressure control was disabled (OFF mode). The cuff pressure in the control group was monitored manually according to standard of care in the ICU. In both groups, the presence of CO_2 levels above the cuff was measured by the AnapnoGuard 100 control unit.

The primary end point of the study was the overall duration and level of around ETT cuff leakage (determined by CO_2 Area under the Curve (AUC)). Secondary end points included number of cuff pressure measurements within the safety accepted range (24 to 40cmH_2O) and number of significant CO_2 leakage (readings at ≥2mmHg in the subglottic space). The non-inferiority hypothesis, compared to the standard of care use today was tested (by the primary endpoint). In addition, the performance safety of the ***AnapnoGuard 100 Respiratory Guard System*** system was evaluated by monitoring and recording device related adverse events.

Results

The average AUC of CO_2 leakage, calculated for the study group was significantly lower compare to control group (0.09±0.04 vs. 0.22±0.32 respectively, This result was found to be statistically significant ($p<0.001$). The significant reduction in CO_2 leakage in study group indicates the efficacy of the ***AnapnoGuard 100 Respiratory Guard System*** (while operating in full clinical mode) in optimizing cuff pressure, and the efficacy of ***AnapnoGuard 100 Respiratory Guard System*** as airway management tool.

Additional aspects of cuff pressure control during mechanical ventilation were:

- Number of cuff pressure measurements within the safety accepted range. Study result indicated that the normalized number of cuff pressure measurements within the safety range in the Study group more than twice the result of the control group (mean ratio Study / Control= 2.03, $P<0.001$).
- Measurements of significant leakages (CO_2) were significantly lower in Study group compare to control group

(0.056 vs. 0.642 respectively, Mean Ratio Study / Control=0.09, $p<0.001$).

Furthermore, no serious or device related adverse events were recorded throughout the study.

These findings further support the performance efficacy of the ***AnapnoGuard 100 Respiratory Guard System*** in optimizing cuff pressure and indicating its efficacy as airway management tool.

Conclusions

The ***AnapnoGuard 100 Respiratory Guard System*** was proven to meet the safety and effectiveness endpoints

Substantial equivalence conclusion

The performance tests and the clinical study that were conducted shows that the ***AnapnoGuard 100 Respiratory Guard System*** is as safe and effective as the listed predicate devices without raising any new questions of safety and efficacy.