Hospitech Respiration Ltd.
℅ Yoram Levy
Qsite General Manager
Qsite
31 Haavoda St.
Binyamina, Israel 30500

Re: K180991
Trade/Device Name: AG 100s
Regulation Number: 21 CFR 868.5750
Regulation Name: Inflatable Tracheal Tube Cuff
Regulatory Class: Class II
Product Code: BSK
Dated: September 13, 2018
Received: September 17, 2018

Dear Yoram 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd D. Courtney -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180991

Device Name
AG100s

Indications for Use *(Describe)*
AG 100s 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Hospitech Respiration

510(K) SUMMARY

AG100s

510(k) Number K180991

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Yoram@qsitemed.com

Trade Name: ***AG100s***

Summary
Preparation Date: **April 9, 2018**
Classification:

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

Device Description:

The ***AG100s*** system is comprised of the following main components:

- The AG100s control unit
- The AnapnoGuard connection kit/harness (AG Connection Kit) connecting a cuffed airway to the ***AG100s*** control unit.
- The AnapnoGuard endotracheal tube (ETT) or another FDA cleared cuffed Airway.
- **Accessories**: including cart, secretions canister (Trap Bottle), rinsing fluid (saline) bag and antibacterial air filter.

AG100s, 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.

Indication for Use:

AG100s 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 and reference devices is claimed:

	K#	**Company**	**Device Name**	**Clearance Date**
Predicate	K150157	Hospitech	AnapnoGuard 100	Feb 16, 2016
Reference	K093126	Hospitech	AnapnoGuard endotracheal Tube	Dec 19, 2015

Comparison with Predicate Devices

The ***AG100s*** primary predicate device is the AnapnoGuard 100 Respiratory Guard System (K150157) since it has the same intended use, clinical indications and implements the same technology.

The AG100s is connected to the same AnapnoGuard ETT that is also part of the K150157 submission. The AnapnoGuard ETT is the same as the AnapnoGuard endotracheal Tube (K093126) that is referenced to this notification.

The AG100s can be interfaced with other suction ETTs, which includes maintaining cuff pressure control and intermittent subglottic suctioning, or to other FDA cleared cuffed airway to maintain preset cuff pressure control. This added ability was tested in performance tests.

The AG100s works, unlike the predicate device, with a disposable single use kit with no direct or indirect contact with any of the system components.

The AG100s is also equipped, unlike the AnapnoGuard 100 Respiratory Guard System, with a general suction port to provide general suction needs with two preset (by the user) suction levels.

Complying with AnapnoGuard ETT or another FDA cleared ETTs:

When used with the AnapnoGuard ETT the ***AG100s*** may conduct full functional mode where cuff pressure is automatically adjusted by the system (within the pressure limits) based on CO_2 level readings above the cuff. Intermittent synchronized rinsing and suction is performed periodically.

When connected to a suction FDA cleared Endotracheal tube, the system offers one mode of operation, which includes maintaining cuff pressure control and intermittent subglottic suctioning.

The user may, at any time, adjust cuff pressure and perform suction by pressing the relevant buttons on the display.

When connected to a standard FDA cleared cuffed Endotracheal tube, the system offers one mode of operation which includes maintaining cuff pressure control.
The user may, at any time, adjust cuff pressure by pressing the relevant buttons on the display.

With any Endotracheal tube, the general suction line (Low Pressure or High Pressure) can be manually activated by pressing on the relevant button on the touch-screen.

Hospitech Respiration

Technological Comparison between the subject device and its predicate device.

Characteristic	*AG 100s system (Submitted)*	*Hospitech's AnapnoGuard 100 system (*K150157*)*	*Comparison*
		GENERAL	
Device Description	The ***AG 100s system*** is an airway management system designed to assist the clinician in achieving proper sealing of the trachea at minimal pressure of the endotracheal tube's cuff in order to minimize induced pressure on the trachea tissue. Achieving the optimal pressure is the responsibility of the clinician. The system includes an Endotracheal Tube, cuff pressure monitor, carbon dioxide (CO2) monitor and irrigation and secretions evacuation modules. The system includes a cuff intra pressure monitoring and control module for measuring and monitoring the cuff pressure. The system performs continuous (every millisecond), online sampling of cuff pressure via the inflation lumen of the endotracheal tube. It also adjusts the cuff pressure within the pressure limits presented by the clinician or alerts the physician to decide if needed to adjust the cuff pressure.	The AnapnoGuard 100 AnapnoGuard system is an airway management system designed to assist the clinician in achieving optimal sealing of the trachea at minimal pressure of the endotracheal tube's cuff in order to minimize induced pressure on the trachea tissue. Achieving the optimal pressure is the responsibility of the clinician. The system includes an Endotracheal Tube, cuff pressure monitor, carbon dioxide (CO_2) monitor and irrigation and secretions evacuation modules. The system includes a cuff intra pressure monitoring and control module for measuring and monitoring the cuff pressure. The system performs continuous (every millisecond), online sampling of cuff pressure via the inflation lumen of the endotracheal tube It also adjusts the cuff pressure within the pressure limits presented by the clinician or alerts the physician to decide if needed to adjust the cuff pressure.	Subject device has the same device description as the predicate device

Characteristic	*AG 100s system (Submitted)*	*Hospitech's AnapnoGuard 100 system (*K150157*)*	*Comparison*
Disinfection	The system does not require disinfection process after use. The device is designed such that secretions pass only through the disposable, single use connection kit, all valves are external "pinch valves" which open and close the pipes by applying external pressure on the silicon pipes. No direct or indirect contact between the secretions and any of part of the control unit.	The system requires disinfection between consecutive clinical uses since the evacuated secretions pass through the internal pipes and valves of the control unit	The AG100s, as described in the left column, routes the secretion through a single use disposable kit, not allowing any contact between the secretion and any of the control unit parts. By this design it removes the need of disinfection process of the control unit (except of external cleaning) and dramatically reduced the risk of cross contamination.

Characteristic	*AG 100s system (Submitted)*	*Hospitech's AnapnoGuard 100 system (*K150157*)*	*Comparison*
Airways	The ***AG100s*** may be used as follows: When used with the AnapnoGuard ETT the ***AG100s*** may conduct full functional mode where cuff pressure is automatically adjusted by the system (within the pressure limits) based on CO_2 level readings above the cuff. Intermittent synchronized rinsing and suction is performed periodically. When connected to a suction FDA cleared Endotracheal tube, the system offers one mode of operation, which includes maintaining cuff pressure control and intermittent subglottic suctioning. The user may, at any time, adjust cuff pressure and perform suction by pressing the relevant buttons on the display. When connected to a standard FDA cleared cuffed Endotracheal tube , the system offers one mode of operation which includes maintaining cuff pressure control. The user may, at any time, adjust cuff pressure by pressing the relevant buttons on the display. With any Endotracheal tube, the general suction line (Low Pressure or High Pressure) can be manually activated by pressing on the relevant button on the touch-screen.	May be interfaced with: 1- AnapnoGuard ETT	Using the device with other FDA cleared devices does not apply any additional risk. All functions with other airways are subset of identical functions with the AnapnoGuard tube. That is: • Suction with other suction tube is identical to "Suction" function with AnapnoGuard ETT. • Constant cuff pressure control allowed with standard cuffed airways, is identical to the "Standby" mode with an AnapnoGuard ETT

Characteristic	*AG 100s system (Submitted)*	*Hospitech's AnapnoGuard 100 system (*K150157*)*	*Comparison*
Indications for single patient use	No	No	Same characteristic as the predicate device
Patient Population	Adults	Adults	Same intended users
CO2 ANALYZER MODULE			
CO_2 analyzer module	CO2 analyzer measures the CO2 levels in the air coming from the subglottic space above the ETT cuff and cuff pressure inflate/deflate accordingly.	Same	Performance test conducted on the subject device. CO2 analyzer module test results supports the substantial equivalence as compared to the predicate device
CO_2 analyzer	Nondispersive infrared sensor with measurement range of 0-10k PPM	Same	
Cuff pressure change based on CO_2 leaks	If Threshold 1 <CO2 < Threshold 2, Increase cuff pressure by 1mmHg If Threshold 2 <CO2, Increase cuff pressure by formula* * (Max pressure limit - current pressure limit)/2 mmHg	Same	
RINSE MODULE			
Rinse module	Include peristaltic pump and sensors with closed loop control on the saline volume.	Include diaphragm pump with open loop control on the saline volume.	Performance test conducted on the subject device rinse module shows that it supports the substantial equivalence as compared to the predicate device rinse module
CUFF PRESSURE CONTROL MODULE			

Characteristic	*AG 100s system (Submitted)*	*Hospitech's AnapnoGuard 100 system (*K150157*)*	*Comparison*
Cuff pressure control module	Regulate the cuff pressure according to determined set point.	Same	Performance test conducted on the subject device in relation to cuff pressure control module show that it supports the substantial equivalence as compared to the predicate device cuff pressure control module
Minimum measured pressure	10 mmHg (13 cmH_2O)	10 mmHg (13 cmH_2O)	
Maximal cuff pressure	50 mmHg (67 cmH_2O)	50 mmHg (67 cmH_2O)	
Control Accuracy	±0.1 mmHg (0.13 cmH_2O)	±0.1 mmHg (0.13 cmH_2O)	
Recording Accuracy	±0.1 mmHg (0.13 cmH_2O)	±0.1 mmHg (0.13 cmH_2O)	
Pressure drop Alarm time	0.2 Sec	0.2 Sec	
Pressure rise alarm time	0.2 Sec	0.2 Sec	
Steady state error	2mmHg (+2.6 cmH_2O)	2mmHg (+2.6 cmH_2O)	
Overshoot	5 – 9 %	6 - 7 %	
Cuff Pressure Control Range	10-50mmHg (13.6 – 68 mmH_2O)	10-50mmHg (13.6 – 68 mmH_2O)	
VACUUM REGULATOR MODULE			
Vacuum regulator module (suction module)	Regulate the vacuum level during suction procedure.	Same	Performance test conducted on the subject device suction module shows that it supports the substantial equivalence as compared to the predicate device suction module
Suction Pressure Range	Subglottic suction: -20 up to -120 mmHg	Subglottic suction: -20 up to -120 mmHg	
Mode of operation	Manual Intermittent	Manual Intermittent	
Closed System	Yes	Yes	
Manual control of vacuum	Yes	Yes	
Evacuation of secretions from above the endotracheal tube's cuff	Yes	Yes	
Gauge accuracy	±1.5% FS	±1% FS	
Regulation Accuracy	±5% FS	±5% FS	

Characteristic	*AG 100s system (Submitted)*	*Hospitech's AnapnoGuard 100 system (*K150157*)*	*Comparison*
Flow Rate	0 to 12 L/min	0 to 15 L/min	
General suction	Provide vacuum range: -20 up to -300 mmHg	N/A	General suction function is identical to the general suction line on any bedside, allowing the clinician to use it for general suction purposes. Standard suction regulators allow suction up to minus 500 and more mmHg. The maximum suction level allowed by the AG100s is 300 mmHg The preset suction level by the user is indicated/displayed on the suction button.

Performance Standards

AG100s 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

Non-Clinical Performance Tests

Performance bench tests were implemented to show that the modifications do not raise different questions of safety and effectiveness. The performance tests were done in order to show that the changes that were

done while upgrading the AnapnoGuard 100 to the ***AG00s*** did not raise any different questions of safety and or effectiveness. The tests demonstrated that the ***AG100s*** is efficient for performing its intended use.

The following performance tests were conducted:

	Name of test
1.	Performance of Suction Module - Comparative test.
2.	Performance of Rinse Module - Comparative test
3.	Performance of Cuff Pressure Control module - Comparative test
4.	Performance of CO2 Reading module - Comparative test
5.	Performance of Cuff Pressure Control Suction with standard and suction ETTs
6.	Performance of General Suction Line module
7.	Performance of new GSS CO_2 sensor Vs. PPS CO_2 sensor
8.	Battery Test
9.	X-ray
10.	RFID and Diathermy
11.	Electrical safety
12.	EMC testing

The conclusions drawn from the nonclinical tests that demonstrate that the ***AG100s*** device is as safe, as effective, and performs as well as or better than the AnapnoGuard 100, the legally marketed predicate device and therefore is substantial equivalent to its predicate device.

Pre-clinical Performance Data

No preclinical tests were conducted.

Summary of Clinical Performance Data

No clinical tests were conducted

Human Factors Validation (Usability) Study

A total of 45 professional team participants, the three professional subjects that are the target population for operating the ***AG100s***, were enrolled in the study.
The results of this usability study clearly indicate that User Manual and GUI of the ***AG100s*** are clear and effective when operated by intended users- hospital professional team.

Substantial equivalence conclusion

The performance tests that were conducted show that the ***AG100s*** is substantially equivalent to the listed predicate device without raising any different questions of safety and effectiveness.