December 29, 2022

Hospitech Respiration Ltd.
℅ Bosmat Friedman
Regulatory Consultant
ProMedoss, Inc.
3521 Hatwynn Rd.
Charlotte, North Carolina 28269

Re: K221477
Trade/Device Name: AG100s
Regulation Number: 21 CFR 868.5750
Regulation Name: Inflatable Tracheal Tube Cuff
Regulatory Class: Class II
Product Code: BSK
Dated: May 18, 2022
Received: May 23, 2022

Dear Bosmat Friedman:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ethan L. Nyberg -S

for James Lee, PhD
Division Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221477

Device Name
AG100s

Indications for Use *(Describe)*

The AG100s is intended to monitor and control the cuff pressures of endotracheal tube (ETT) or tracheostomy tube (TT) and to evacuate secretions from the subglottic space above the cuff during mechanical ventilation.
1. When used with a standard ETT or TT, the device automatically maintains the cuff pressure as pre-set by the user.
2. When used with ETT or TT with suction line, the device automatically maintains the cuff pressure as pre-set by the user and performs intermittent evacuation of subglottic secretions from above the tube's cuff.
3. When used with ETT with suction and venting lines (e.g., AG ETT), the device automatically maintains the cuff pressure as pre-set by the user, or automatically adjusts the cuff pressure based on monitoring of the Carbon Dioxide (CO2) concentration above the cuff. In addition, it performs evacuation, or rinsing and evacuation of subglottic secretions from above the 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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510(K) SUMMARY
[as required by section 807.92(c)]
AG100s
510(k) Number K221477

5.1 SUBMITTER

Applicant's Name:
Hospitech Respiration Ltd.
15 Atir Yeda
Kfar-Saba, 4464312, Israel
TEL: 972-3-919-1648
FAX: 972-3-919-1647

Contact Person:
Bosmat Friedman
Regulatory Affairs Consultant
3521 Hatwynn Rd.
Charlotte, NC 28269
Phone: 980-308-1636
bosmat.f@promedoss.com

Date Prepared:
September 14, 2022

5.2 DEVICE

Trade Name:
AG100s

Classification Code: **Classification Name:** Cuff, Tracheal Tube, Inflatable
Product Code: BSK
Regulation No: 868.5750
Class: 2
Review Panel: Anesthesiology

5.3 PREDICATE DEVICES

Predicate Device 1 (Primary)

- AG100s, by Hospitech Respiration Ltd., Product code BSK cleared Under: K180991.

Predicate Device 2 (Secondary)

- IntelliCuff, manufactured by Hamilton Medical AG., cleared under K150893; Product Code: BSK.

5.4 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.

Additional device components include cart, secretions canister (Trap Bottle), rinsing fluid (saline) bag and antibacterial air filter.

When the AG100s, is connected to AG ETT, it monitors leaks between endotracheal 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 AG ETT). 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.
The AG100s also performs cuff pressure monitoring and control in standard FDA cleared TTs and ETTs; depending on the tube type, the system may also perform secretions removal.

5.5 INDICATIONS FOR USE

The AG100s is intended to monitor and control the cuff pressures of endotracheal tube (ETT) or tracheostomy tube (TT) and to evacuate secretions from the subglottic space above the cuff during mechanical ventilation.

1. When used with a standard ETT or TT, the device automatically maintains the cuff pressure as pre-set by the user.
2. When used with ETT or TT with suction line, the device automatically maintains the cuff pressure as pre-set by the user and performs intermittent evacuation of subglottic secretions from above the tube's cuff.
3. When used with ETT with suction and venting lines (e.g., AG ETT), the device automatically maintains the cuff pressure as pre-set by the user, or automatically adjusts the cuff pressure based on monitoring of the Carbon Dioxide (CO_2) concentration above the cuff. In addition, it performs evacuation, or rinsing and evacuation of subglottic secretions from above the tube's cuff.

5.6 SUBSTANTIAL EQUIVALENCE

The AG100s is substantially equivalent to the predicate device based on the following:

Intended Use
The intended use of the proposed device remains unchanged. The indication for use has been modified to include the ability to connect to TT as well as to provide

clarifications regarding device functionality when connected to various airway tubes.

Technology
The proposed device modifications introduce the ability to connect the system to TT through minor GUI modifications. All changes have been validated demonstrating that the device functions as intended. Testing demonstrates that the modified AG100s functions in an equivalent manner as the previously cleared AG100s.

Discussion
The modified AG100s has the same intended use as the previously cleared AG100s, and a slightly modified indications for use statement (for clarification purposes). The main technological difference between the devices is the ability to connect the AG100s to a TT as well as ETT.
Verification and Validation testing demonstrated that the revised device is substantially equivalent to the previously cleared AG100s. Consequently, the AG100s is as safe and effective as its predicates without raising any new safety and/or effectiveness concerns.

Substantial Equivalency Table

Characteristics	*Subject Device* AG100s System	*Primary Predicate* AG100s (K180991)	*Comments*
Manufacturer	Hospitech Respiration, Ltd.	Hospitech Respiration, Ltd.	Same
510(k) Number	TBD	K180991	--
Product Code(s)	BSK	BSK	Same
Regulation	868.5750	868.5750	Same
Class	2	2	Same
Indications for Use	The AG100s is intended to monitor and control the cuff pressures of endotracheal tube (ETT) or tracheostomy tube (TT) and to evacuate secretions from the subglottic space above the cuff during mechanical ventilation. a. When used with a standard ETT or TT, the device automatically maintains the cuff pressure as pre-set by the user. b. When used with ETT or TT with suction line, the device automatically maintains the cuff pressure as pre-set by the user and performs intermittent evacuation of subglottic secretions from above the tube's cuff. c. When used with ETT with suction and venting lines (e.g., AG ETT), the device automatically maintains the cuff pressure as pre-set by the user, or automatically adjusts the cuff pressure based on monitoring of the Carbon Dioxide (CO_2) concentration above the cuff. In addition, it performs evacuation, or rinsing and evacuation of subglottic secretions from above the tube's cuff.	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.	Same overall intended use. Indications for use slightly modified to include the ability to connect to TT as well as provide clarity regarding device functionality with various tubes. Changes have been validated via performance testing. No new question of safety and effectiveness.
Indications for single patient use	No	No	Same
Allows tube replacement without disconnecting patient from ventilator	Yes, both TT and ETT	Yes, ETT only	Similar, in predicate device TT was not used.
Patient Population	Adults	Adults	Same
Biocompatibility	No new patient contacting materials	All materials that come in contact with the patient body	Same

Characteristics	*Subject Device* AG100s System	*Primary Predicate* AG100s (K180991)	*Comments*
		or liquids are biocompatible and compliant with ISO 10993-1	
Latex Free	Yes	Yes	Same
Power Supply	100-240 V with backup battery	100-240 V with backup battery	Same
CO_2 analyzer module	CO_2analyzer measures the CO_2levels in the air coming from the subglottic space above the ETT cuff and cuff pressure inflate/deflate accordingly.	CO_2analyzer measures the CO_2levels in the air coming from the subglottic space above the ETT cuff and cuff pressure inflate/deflate accordingly.	Same
Rinse module	Includes peristaltic pump and sensors with closed loop control on the saline volume.	Includes peristaltic pump and sensors with closed loop control on the saline volume.	Same
Cuff pressure control module	Regulate the cuff pressure according to a pre-determined set point.	Regulate the cuff pressure according to a pre-determined set point.	Same
Cuff Pressure Control Range	10-50mmHg (13.6 – 68 mmH2O)	10-50mmHg (13.6 – 68 mmH2O)	Same
Vacuum regulator module (suction module)	Regulates the vacuum level during suction procedure.	Regulates the vacuum level during suction procedure.	Same
Suction Pressure Range	Subglottic suction: -20 up to -120 mmHg	Subglottic suction: -20 up to -120 mmHg	Same
Mode of operation	Manual Intermittent	Manual Intermittent	Same
Closed System	Yes		Same
Manual control of vacuum	Yes		Same
Evacuation of secretions from above the endotracheal tube's cuff	Yes	Yes	Same
Flow Rate	0 to 12 L/min	0 to 12 L/min	Same
General suction	Not available	Yes	Different; the general suction option was removed as it was not regularly used by end user. No impact on device safety or effectiveness.

5.7 PERFORMANCE DATA

In order to support the proposed modifications, the following tests were conducted:

- Comparative AG100s Cuff pressure control + suction performance when connected to ETTs & TTs
- Software System V&V Test
- AG100s Usability Validation

5.8 CONCLUSION

Hospitech Respiration has demonstrated that the AG100s is substantially equivalent to the predicate device. Differences between the AG100s and the predicate device do not raise new questions of safety or effectiveness.