August 13, 2020

Biovo Technologies Ltd.
% Bosmat Friedman
Regulatory Consultant
ProMedoss, Inc.
3521 Hatwynn Rd.
Charlotte, North Carolina 28269

Re: K192611
Trade/Device Name: Cuffix
Regulation Number: 21 CFR 868.5750
Regulation Name: Inflatable Tracheal Tube Cuff
Regulatory Class: Class II
Product Code: BSK
Dated: August 10, 2020
Received: August 11, 2020

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,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192611

Device Name
Cuffix

Indications for Use *(Describe)*
The Cuffix is intended to measure and regulate, through passive control, the intracuff pressure of Endotracheal tubes, Tracheotomy tubes and Laryngeal Masks Airways (LMAs) (supraglottic airways). The device is intended for single patient use, under medical supervision in hospitals, pre-hospital (EMS), extended care facilities or outpatient clinics, where a patient may be intubated.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

[as required by section 807.92(c)]

Cuffix

510(k) Number K192611

5.1 SUBMITTER

Applicant's Name:
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Contact Person:
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Date Prepared:
August 10, 2020

5.2 DEVICE

Trade Name:
Cuffix

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

5.3 PREDICATE DEVICE

Primary predicate device:

- AG Cuffill, manufactured by Hospitech Respiration Ltd., cleared under K122721, product code: BSK

Reference device:

- PressureEasy Cuff Pressure Controller, manufactured by Smith Medical Inc., cleared under K833327, product code: BSK.

5.4 DEVICE DESCRIPTION

The Cuffix is a battery-operated cuff pressure controlling device which is intended to be used with ventilation tubes (ETT, Tracheostomy, LMA) It is a single patient-use, non-sterile device designed to be used continuously for up to 14 days.
The device is connected to the pilot balloon of airways with inflatable air-filled cuffs via the device's extension line. The operating range of the Cuffix is 0-99 cmH_2O.
The device body houses the passive pressure mechanism component as well as the active pressure monitoring mechanism which displays the cuff pressure on the digital screen. An indicator light provides an additional visual aid to indicate whether the cuff pressure is at the correct pressure (green) or is the pressure is out of the set range (red).
The elastic band hanger allows to attach the Cuffix as needed (e.g., to the ventilation circuit, the patient bed rail, etc.).

5.5 INDICATIONS FOR USE

The Cuffix is intended to measure and regulate, through passive control, the intracuff pressure of Endotracheal tubes, Tracheotomy tubes and Laryngeal Masks Airways (LMAs) (supraglottic airways). The device is intended for single patient use, under medical supervision in hospitals, pre-hospital (EMS), extended care facilities or outpatient clinics, where a patient may be intubated.

5.6 SUBSTANTIAL EQUIVALENCE

The Cuffix has the same intended use and substantially similar technological characteristics as both the primary predicate device and reference device. Furthermore, comparative testing has demonstrated that the device performs similarly to both the Cuffill and PressureEasy predicate devices. Consequently, it is clear that the Cuffix is as safe and effective as its primary predicate and reference devices without raising any new safety and/or effectiveness concerns. Any differences between the devices have been addressed through testing and validations and, therefore, negate any safety or effectiveness concerns.

	Cuffix	**AG Cuffill**	**PressureEasy Cuff Pressure Controller**
510k Number	--	K122721	K833327
Device Classification	2	2	2
Classification Product Code	BSK	BSK	BSK
Regulation Number	868.5750	868.5750	868.5750
Intended Use	The Cuffix is intended to measure and regulate, through passive control, the intracuff pressure of Endotracheal tubes,	The Hospitech AG Cuffill is intended to measure and regulate the intra-cuff pressure of Endotracheal tubes, Tracheotomy tubes and	To maintain the HVLP (high volume low pressure) cuff pressure, of an endotracheal tube within the range of

	Cuffix	**AG Cuffill**	**PressureEasy Cuff Pressure Controller**
	Tracheotomy tubes and Laryngeal Masks Airways (LMAs) (supraglottic airways). The device is intended for single patient use, under medical supervision in hospitals, pre-hospital (EMS), extended care facilities or outpatient clinics, where a patient may be intubated	Laryngeal Masks Airways (LMAs) (supraglottic airways). The Hospitech AG Cuffill is used under medical supervision in hospitals, pre-hospital (EMS), extended care facilities and outpatient clinics, where a patient may be intubated.	20 to 30 cm H2O through passive control.
Prescription use	Yes	Yes	Yes
Technical Characteristics			
Type of control	Passive	Active- syringe inflation by user	Passive
Cuff pressure intended use range	20-30cmH2O	0-99cmH2O	20-30cmH2O
Internal pressure reservoir (balloon)	Elastic inner balloon that expands and contracts as air flows to and from the cuff	No internal pressure reservoir	Elastic inner balloon that expands and contracts as air flows to and from the cuff
Numerical pressure screen	Yes	Yes	No
Alarm when pressure is out of range	Yes – blinking red light	No	No
Accuracy	±3cmH_2O	±2cmH_2O	N/A
Damping function of air flow from cuff to the balloon	Yes	N/A	No
Free flow of air from the balloon to the cuff	Yes	N/A	Yes
Continuous monitoring of cuff pressure	Yes	No	Yes
Continuous stabilization of cuff pressure	Yes	No	Yes
Inflation by syringe or cuff pressure monitor	Yes	N/A	Yes

	Cuffix	**AG Cuffill**	**PressureEasy Cuff Pressure Controller**
Connection to pilot balloon using luer connector	Yes	Yes	Yes
Single patient use	Yes	No	Yes
Operation time	Up to 2 weeks	100 operations (measurements)	Not limited
Patient contact	Does not come in direct or indirect contact with the patient or the user	Does not come in direct or indirect contact with the patient or the user	Does not come in direct or indirect contact with the patient or the user
Provided sterile	No	No	No

5.7 PERFORMANCE DATA

Non-Clinical Performance Testing:

The Cuffix device has undergone and successfully passed the following tests:

- Shelf-life
- EMC and electrical safety
- Performance verification and validation testing (including: battery life, line kinking, response time, detachment force testing, etc.)
- Comparative testing (to both Cuffill and PressureEasy predicates)
- Compliance with ISO 80369

Animal and Clinical Performance Testing:

Animal and clinical performance data was not included.

5.8 CONCLUSION

Biovo Technologies Ltd. believes that Cuffix is substantially equivalent to the AG Cuffill primary predicate device and the PressureEasy reference device. It does not introduce new indications for use, has substantially equivalent technological and performance characteristics, and therefore does not introduce different questions safety and effectiveness.