June 2, 2023

PEEP Medical, LLC
℅ Paul Dryden
Consultant
131 Bay Point Drive
St. Petersburg, Florida 33704

Re: K222018
Trade/Device Name: Breathe+
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive Spirometer
Regulatory Class: Class II
Product Code: BWF
Dated: April 16, 2023
Received: April 17, 2023

Dear Paul Dryden:

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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant 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)*
K222018

Device Name
Breathe+

Indications for Use *(Describe)*
The Breathe+ is intended for use as a Positive Expiratory Pressure Device to help prevent or reverse atelectasis in adult patients needing PEP therapy. Intended for single-patient, multi-use in a hospital or home care setting.

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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Date Prepared:	02-Jun-2023
Sponsor:	PEEP Medical, LLC 9230 Katy Freeway, Suite 600 Houston, TX 77055
Official Contact:	Sean Boutros, MD Founder
Submission Correspondent:	Paul Dryden ProMedic, LLC
Proprietary or Trade Name:	Breathe+
Common/Usual Name:	Incentive Spirometer
Classification Name:	Product Code – BWF – Spirometer, Therapeutic (Incentive)
Predicate Device:	DHD Diemolding Healthcare Division – Therapep – K962749
Common/Usual Name:	Incentive Spirometer
Classification Name:	Product Code – BWF – Spirometer, Therapeutic (Incentive)
Reference Device:	D R Burton - iPEP System and vPEP – K160636
Common/Usual Name:	Incentive Spirometer
Classification Name:	Product Code – BWF – Spirometer, Therapeutic (Incentive)
Device Description:	The subject device provides PEP only. The applications of PEEP (PEP) in patients with lung disease is a well-known entity; oxygenation depends on the FiO2 and PEEP, and manipulation of any of these parameters should raise oxygenation in intubated patients. Patients with emphysema instinctively practice pursed lip breathing in order to increase the lung pressure, decrease alveolar collapse and dead space, and improve oxygenation.

The subject device is an oral device that provides positive expiratory airway pressures to enhance expiratory muscle strength while preventing and reversing atelectasis. Furthermore, the device is hands-free.

Principle of Operation: Upon inhalation, the "flap" valve opens and one can inhale with limited resistance. During exhalation, the "flap" valve closes and the front plate is pushed open under resistance, ~ 8 cm H_2O, that is set by the bands. The exhaled breath exits through the sides.

Indications for Use: The Breathe+ is intended for use as a Positive Expiratory Pressure Device to help prevent or reverse atelectasis in adult patients needing PEP therapy. Intended for single-patient, multi-use in a hospital or home care setting.

Description	Subject Device	Predicate Device	Reference Device	Differences
Sponsor	PEEP Medical	DHD Diemolding Healthcare Division	D R Burton	
510(k) Number	TBD	K962749	K160636	
Model Name	Breath+	TheraPEP	iPEP System and vPEP	
Classification	Class II Device BWF 21 CFR 858.5690	Class II Device BWF 21 CFR 858.5690	Class II Device BWF 21 CFR 858.5690	Identical
Indications for use	The Breathe+ is intended for use as a Positive Expiratory Pressure Device to help prevent or reverse atelectasis in adult patients needing PEP therapy. Intended for single-patient, multi-use in a hospital or home care setting.	The DHD TheraPEP is intended for use as a Positive Expiratory Pressure Device for patients suffering from Cystic Fibrosis, lung diseases with secretory problems, and to prevent or reverse atelectasis.	The D R Burton iPEP Therapy System is intended for use as a Positive Expiratory Pressure (PEP) by patients capable of generating an exhalation flow of 10 lpm for 3-4 seconds and an Incentive Spirometer as an inspiratory, deep breathing positive exerciser. Intended for single-patient, multi use. iPEP System for hospital and clinical settings.	The subject device is intended to prevent or reverse atelectasis.

			vPEP for hospital, clinical, and home care setting.	
Environment of Use	Hospital and home under HCP direction	Clinical settings	Hospital, clinical, and home settings	Similar
Patient Population	Patients requiring inspiratory exercise and / or PEP therapy	Patients requiring inspiratory exercise and / or PEP therapy	Patients requiring inspiratory exercise and / or PEP therapy and capable of generating an exhalation flow of 10 lpm for 3-4 seconds	Similar
Principle of Operation (PEP)	Resistor Mouthpiece	Resistor Pressure range indicator Pressure adapter Mouthpiece	Flap valve, which generates oscillation during exhalation One-way valve Mouthpiece	Similar
Use with a nebulizer	No	Yes	No	Use without a nebulizer does not raise new concerns of safety or effectiveness.
Duration of Use	Prolonged < 30 days	Prolonged < 30 days	Prolonged < 30 days	Similar
Biocompatibility ISO 10993-1	Surface Contact Mucosal membrane Externally Communicating Tissue Duration of Use – prolonged (>24 hours, <30 days)	Surface Contact Mucosal membrane Externally Communicating Tissue Duration of Use – prolonged (>24 hours, <30 days)	Surface Contact Mucosal membrane Externally Communicating Tissue Duration of Use – limited (<24 hours)	Similar
Performance Testing				
Exhalation Resistance (cmH_2O)	4.4 cmH_2O @ 20 lpm 8.5 cmH_2O @ 30 lpm 9.7 cmH_2O @ 40 lpm	Unknown	Min – 0 cmH_2O @ 5 lpm Min – 2.5 cmH_2O @ 25 lpm Max – 5.5 cmH_2O @ 5 lpm Max – 25.1 cmH_2O @ 25 lpm	The exhalation resistance does not raise new concerns of safety or effectiveness.
Single patient, multi-use	Yes	Yes	Yes	Similar
Clean with soapy water	Yes	N/A	N/A	Cleaning the device does not raise concerns of safety or effectiveness. Test results did not show a degradation in performance.

Indications for Use –
The indications for use are similar for the proposed device when compared to the predicate –
Discussion – Each device is indicated to provide PEP during patient exhalation, though the subject device makes no claims regarding Cystic Fibrosis.

Technology and construction –
The technology of using a resistor to create PEP during exhalation is common to both devices.
Discussion – There are no technological differences which would raise different questions of safety or effectiveness between the proposed device and the predicate.

Environment of Use –
The environments of use are similar – home and clinical settings.
Discussion – The environments of use are similar. Home use is supported by the reference device.

Patient Population –
The patient population of the proposed device and predicate are the same.
Discussion – The patient population is equivalent to the predicate.

Non-Clinical Testing Summary –

Bench testing –
We performed the following tests: Resistance to flow, and PEP values for repeatability and accuracy. These tests were performed on final, finished samples both pre- and post-aging as well as post-repeated cleaning.
Discussion – The device performance was tested and does not raise any new concerns of safety or effectiveness.

Biocompatibility –
Contact Type and Duration: Surface Contact, Mucosa, Externally Communicating, Tissue; prolonged (>24 hours, <30 days)
Discussion – The proposed device materials, contact type, and duration are identical to the device materials that were cleared under K062104. A Material Certification was used to support the Biocompatibility.

Discussion of Differences –

The design, performance and function of the device does not raise any significant differences that would raise concerns of safety or effectiveness.

Substantial Equivalence Conclusion

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the subject device and predicate have been found to be substantially equivalent.