February 2, 2024

Enchant Tek Co. Ltd.
Leonard Ling
QA/RA Supervisor
No. 210 Xiangzhong Rd.
Dongshan Township
Yilan County, 26950
Taiwan

Re: K233855
Trade/Device Name: AllPEP
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive Spirometer
Regulatory Class: Class II
Product Code: BWF
Dated: December 4, 2023
Received: December 5, 2023

Dear Leonard Ling:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233855

Device Name
AllPEP

Indications for Use *(Describe)*
The Enchant AllPEP is intended for use as a Positive Expiratory Pressure (PEP) by patients aged 18 years and older. Patients must be capable of generating an exhalation flow of 10 lpm for 3-4 seconds to promote secretion clearance. This device may be used to prevent or reverse atelectasis and as an inspiratory, deep breathing positive exerciser. It may be used in hospital and clinical settings.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Date Prepared: February 2, 2024

Sponsor:
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Tel +886- 03-959-3500

Sponsor Contact: Ling Leonard - QA/RA Supervisor

Submission Correspondent: Paul Dryden
ProMedic, LLC

Proprietary or Trade Name: AllPEP
Common/Usual Name: PEP device
Classification Name: Spirometer, therapeutic (incentive)
21CFR 868.5690
Product Code: BWF

Predicate Device: DHD Acapella K991561
Common/Usual Name: Spirometer, therapeutic (incentive)
Classification Name: 21CFR 868.5690
Product Code: BWF

Device Description: AllPEP provides PEEP during user exhalation and features a mechanism which provides oscillations during exhalation as well.

Principle of Operation: The oscillating positive exhalation pressure device, AllPEP, includes a housing, a top cover, and an oscillating mechanism. The patient inhales room air through a one-way valve and when exhaling the exhaled gas is directed through the upper portion of the device which contains a swinger mechanism to oscillate the air, causing the air to vibrate.

Indications for Use:
The Enchant AllPEP is intended for use as a Positive Expiratory Pressure (PEP) by patients aged 18 years and older. Patients must be capable of generating an exhalation flow of 10 lpm for 3-4 seconds to promote secretion clearance. This device may be used to prevent or reverse atelectasis and as an inspiratory, deep breathing positive exerciser. It may be used in hospital and clinical settings.

Patient Population:
Patients 18 years and older who are capable of generating an exhalation flow of 10 lpm for 3-4 seconds.

Environments of use:
For hospital and clinical settings.

Substantial Equivalence Discussion
The table below compares the key features of the proposed with the identified predicate - DHD Acapella K991561. The comparison demonstrates that the subject device is substantially equivalent to the predicate device.

- **Indications for Use -**
  The indications for use are similar for the subject device when compared to the predicate device.
  Discussion – Since the predicate, newer cleared PEP devices have more details within the indications for use. We have added this information, it does not however raise different questions of safety or effectiveness.

- **Technology and construction** -
  The technology and principle of operation is similar for the subject device when compared to the predicate device.
  Discussion – While the predicate may have a different means of creating oscillation, there are a number of cleared PEP devices which also have slightly different ways of creating oscillations during the exhalation cycle. This difference does not raise different concerns of safety or effectiveness.

- **Environment of Use -**
  The environments of use are similar to predicate which are hospital and clinical settings.
  Discussion - The environments of use are similar.

- **Patient Population -**
  The patient population for the subject device is patients requiring secretion clearance and those who may have atelectasis. They should be capable of generating an exhalation flow of 10 lpm for 3-4 seconds.
  Discussion - The subject and predicate device patient populations are similar.

Non-Clinical Testing Summary -

Bench testing -
The following tests were performed to demonstrate substantial equivalence:
- Aging and post-aging performance
- Cleaning validation
- Post-cleaning performance
- Frequency (Hz)
- Amplitude (cmH20)
- Pressure at min / max settings (cmH20)

Discussion - The test results are similar to the predicate and within pre-defined acceptance criteria.

Biocompatibility –
According to IS0 10993-1 and the *FDA Guidance* related to biocompatibility from 2020, the subject device is considered:

- External Communicating
- Tissue Contacting
- Prolonged duration of use (>24 hours, <30 days)

For those materials in direct contact, they would be considered:

- Surface Device
- Mucosal Membrane
- Prolonged duration of use (>24 hours, <30 days)

Based upon IS0 10993-1, the sponsor has performed the following biocompatibility tests for the subject device:

- ISO 10993-5:2009 - Cytotoxicity
- ISO 10993-10:2010 - Sensitization and Intracutaneous Reactivity
- ISO 10993-11:2017 - Material-Mediated Pyrogenicity
- ISO 10993-18:2020 - Chemical Characterization and Risk Assessment
- ISO 18562-2:2018 - Particulate Matter testing
- ISO 18562-3:2018 - Volatile Organic Compounds (VOC) with risk assessment

Discussion – The subject device was found to meet the applicable requirements for biocompatibility safety for the intended population.

Discussion of Differences
There are no significant differences in indications for use, population, use environments, technological characteristics or performance which raise different concerns of safety compared to the predicate and thus should be found to be substantially equivalent.

Substantial Equivalence Conclusion
Through performance testing, design, and non-clinical testing the proposed device and predicate have been found to be substantially equivalent.

	Subject Device	Predicate Device	Subject and Predicate Comparison
Company	Enchant Tek Co., Ltd.	DHD Acapella	
510(k)	K230622	K991561	
Classification No. & Product code	868.5690 BWF - spirometer, therapeutic (incentive)	868.5690 BWF - spirometer, therapeutic (incentive)	Identical
Indications for Use	The Enchant AllPEP is intended for use as a Positive Expiratory Pressure (PEP) by patients 18 years and older. Patients must be capable of generating an exhalation flow of 10 lpm for 3-4 seconds to promote secretion clearance. This device may be used to prevent or reverse atelectasis and as an inspiratory, deep breathing positive exerciser. It may be used in hospital and clinical settings.	Indicated for use as a Positive Expiratory Pressure (PEP) Device • improves clearance of secretions • may reduce the need for postural drainage • facilitates opening of airways in patients with Cystic Fibrosis, COPD, asthma, and lung diseases with secretory problems • may be used to prevent or reverse atelectasis	Similar More recent PEP clearances have included the environment of use and target population in the indications statement. This does not change the intended use.
Environments of Use	Hospital and clinical settings	Hospital, clinical and home care settings	Similar, but not for home use
Prescriptive	Yes	Yes	Similar
Patient Population	Patients requiring PEP therapy aged 18 years and older. Patient capable of generating an exhalation flow of 10 lpm for 3-4 seconds	Patients requiring PEP therapy	Similar
Single Patient, multi-use	Yes	Yes	Similar
Patient Interface	Mouthpiece	Mouthpiece	Similar
Basic Components	Swinging Flap valve which generates oscillation during exhalation One-way valve for inhalation Mouthpiece	Rocker which generates oscillation during exhalation One-way valve for inhalation Mouthpiece	Similar The principle of operation is the oscillation during airflow. This is similar to the predicate device and does not raise different questions of safety and effectiveness
Mean frequency range (Hz)	5lpm - 9.82 10lpm - 9.96 15lpm - 11.85 20lpm - 13.01 25lpm - 14.89 30lpm - 16.32	Not published	Similar based on bench testing of subject device and predicate

	Subject Device	Predicate Device	Subject and Predicate Comparison
Mean amplitude Pressure (cmH20)	5lpm - 3.24 10lpm - 6.31 15lpm - 8.31 20lpm - 9.42 25lpm - 9.12 30lpm - 9.17	Not published	Similar based on bench testing of subject device and predicate
Lowest Pressure (cmH20)	5lpm - 0.50 10lpm - 0.78 15lpm - 2.09 20lpm - 4.00 25lpm - 7.26 30lpm - 10.75	Not published	Similar based on bench testing of subject device and predicate
Highest Pressure (cmH20)	5lpm - 3.74 10lpm - 7.10 15lpm - 10.40 20lpm - 13.42 25lpm - 16.38 30lpm - 19.92	Not published	Similar based on bench testing of subject device and predicate
Cleaning method	Neutral dishwashing agent Single patient, multi-use	Cleaning instructions not provided Single patient, multi-use	Similar based on bench testing of subject device and predicate
Performance testing	Aging and post-aging performance Cleaning and post-cleaning performance Cleaning validation Transportation - shock and vibration Frequency (Hz) Amplitude (cmH2O) Pressure at min / max settings (cmH2O)	Frequency (Hz) Amplitude (cmH2O) Pressure at min I max settings (cmH2O)	Similar
Type of patient contact with materials	Externally communicating/Tissue Surface contact /mucosa Prolonged duration (>24 hours, ＜ 30 days)	Not published	Patients are instructed to replace device every 30 days.