January 15, 2021

AirPhysio Pty Ltd
% Rafael Aguila
Responsible Third-Party Official
Accelerated Device Approval Services
6800 S.W. 40th Street, Ste. 403
Ludlum, Florida 33155

Re: K203209
Trade/Device Name: AirPhysio Positive Expiratory Pressure (PEP) Device
Regulation Number: 21 CFR 868.5665
Regulation Name: Powered Percussor
Regulatory Class: Class II
Product Code: BYI
Dated: January 5, 2021
Received: January 6, 2021

Dear Rafael Aguila:

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, Ph.D.
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)*
K203209

Device Name
AirPhysio Positive Expiratory Pressure (PEP) Device

Indications for Use *(Describe)*
AirPhysio is indicated for use as a Positive Expiratory Pressure (PEP) Device for improving the clearance of mucus secretions from the airways.

AirPhysio vibrates the airway walls to assist in loosening mucus and intermittently increases endobronchial pressure so that the airway patency can be maintained during exhalation, reducing the potential of mucus becoming trapped as it moves up the airways.

The device may also be useful in the removal of mucus from patients who have chronic bronchitis or bronchiectasis and in conjunction with a medical need for positive expiratory pressure (PEP) therapy.

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: 15 JANUARY 2021

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Proprietary / Trade Name: AirPhysio Positive Expiratory Pressure (PEP) Device

Regulation Description: Powered Percussor

Regulation Number: 21 CFR 868.5665, Class II

Product Code: BYI

Predicate Device: Flutter D – Clement Clarke – K972859

Device Description:

AirPhysio is a small, handheld expiration resistance device, consisting of a hardened plastic mouthpiece at one end, a plastic cover with an opening at the other end, and a valve on the inside created by a high- density stainless-steel ball resting in a plastic conical cone. Exhalation through the device causes vibrations, assisting to loosen mucus from the airways. The resistance is increased by tilting the device.

The subject device is provided non-sterile for reprocessing in a home environment and has no accessories or configuration options.

Indications for Use:

AirPhysio is indicated for use as a Positive Expiratory Pressure (PEP) Device for improving the clearance of mucus secretions from the airways.

AirPhysio vibrates the airway walls to assist in loosening mucus and intermittently increases endobronchial pressure so that the airway patency can be maintained during exhalation, reducing the potential of mucus becoming trapped as it moves up the airways.

The device may also be useful in the removal of mucus from patients who have chronic bronchitis or bronchiectasis and in conjunction with a medical need for positive expiratory pressure (PEP) therapy.

Technological Characteristics

The principle of the AirPhysio as a mucus clearance device is its ability to vibrate the airways (which loosens mucus from airway walls) and intermittently increase endobronchial pressure (which maintains patency duringexhalation).

The moveable stainless-steel ball inside the device opposes the patient's exhalation which creates a resistance due to the weight of the ball. During exhalation, the force of gravity on the ball and the pressure of the exhaled air causes the ball to vibrate (bounce) up and down. This cycle repeats itself throughout each exhalation.

During the exhalation, the positive expiratory pressure (PEP) combined with the vibrations of the rapidly oscillating steel ball, help to loosen mucus and mobilize secretions from deep within the airways to the throat for expectoration.

Comparison of Technological Characteristics with the Predicate Device

Oscillating high frequency PEP (OPEP) devices combine both PEP and airway oscillation techniques and is the technological principle being employed in both the subject and predicate devices.

In both subject and predicate devices, as exhaled gas passes through the device, a steel ball vibrates vertically within its casing, causing airflow vibrations or oscillations. The angle at which the subject or predicate devices are held by the patient affects the amount of effort needed to cause the steel ball to vibrate, which affects the expiratory flow and thus controls the frequency, amplitude of the oscillations and the positive expiratory pressure (PEP).

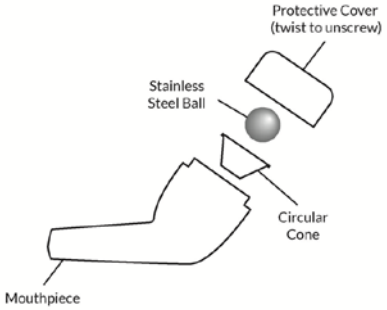
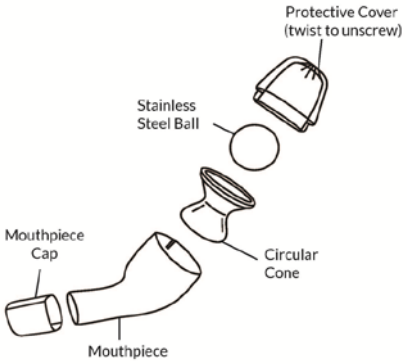
In comparison, both the subject and predicate devices are based on the same technological characteristics including:

- Same pipe-like shape and similar size
- Both devices use a weighted metal ball resting in a cone to create the PEP
- The same weighted metal ball is used to create oscillations in both devices
- Both devices use a tilt angle to modify the PEP and oscillation frequency

The following technological differences exist between the subject and predicate device:

- Material composition of predicate device is made from polypropylene, while to subject is made from polycarbonate, but appears similar in operation for both the predicate and subject devices
- The devices have non-critical variations to their internal dimensions
- The subject uses a dual cone instead of the single cone used in the predicate
- The subject device includes a mouthpiece cover for improved hygiene
- The subject device includes a child-resistant protective cover.

Product Characteristics

	PREDICATE DEVICE - Flutter D	**SUBJECT DEVICE - AirPhysio**
510k Number	K972859	K203209
Manufacturer	Clement Clarke	AirPhysio Pty Ltd
Device Design	 Device Components: 1 – Main body & mouthpiece (Poly-propylene plastic) 2 – Circular Cone (Poly-propylene plastic) 3 – Stainless Steel Ball (Stainless Steel) 4 – Protective Cover (Poly-propylene plastic)	 Device Components: 1 – Mouthpiece cap (Poly-urethane plastic) 2 – Main body & mouthpiece (Poly-carbonate plastic) 3 – Circular cone (Poly-carbonate plastic) 4 – Stainless steel ball (stainless steel) 5 – Child resistant protective cover (Poly-carbonate plastic)
Substantial Equivalence Discussion	The predicate and subject devices are designed using similar design principles consisting of the same pipe-like shape and incorporating a metal ball, cone, mouthpiece and vented cover.	

	PREDICATE DEVICE - Flutter D	**SUBJECT DEVICE - AirPhysio**
Indications for Use / Patient Population	The efficacy of the Flutter D as a mucus clearance device for cystic fibrosis patients is based on its ability to: • Vibrate the airway (which loosens mucus from the airway walls). Intermittently increase endobronchial pressure (to maintain the patency of airways during exhalation, so that mucus does not become trapped as it moves up the airways); • accelerate expiratory airflow to facilitate the upward movement of mucus through airways so that it can be coughed out; • It may also be used for removal of mucus from the airways of patients who have chronic bronchitis or bronchiectasis and in conjunction with medical need for Positive Expiratory Pressure (PEP) Therapy.	AirPhysio is indicated for use as a Positive Expiratory Pressure (PEP) Device for improving the clearance of mucus secretions from the airways. • AirPhysio vibrates the airway walls to assist in loosening mucus and intermittently increases endobronchial pressure so that the airway patency can be maintained during exhalation, reducing the potential of mucus becoming trapped as it moves up the airways. • The device may also be useful in the removal of mucus from patients who have chronic bronchitis or bronchiectasis and in conjunction with a medical need for positive expiratory pressure (PEP) therapy.
Substantial Equivalence Discussion	The predicate and subject devices are substantially equivalent in their intended use. Both devices are designed to assist patients to mobilise mucus secretions using positive expiratory pressure (PEP) therapy and to assist in the treatment of similar respiratory conditions.	

	PREDICATE DEVICE - Flutter D	**SUBJECT DEVICE - AirPhysio**
Principles of Operation / Technological Characteristics	The principle of the FLUTTER® as a mucus clearance device is based on its ability to: (1) vibrate the airways (which loosens mucus from the airway walls); (2) intermittently increase endobronchial pressure (which helps maintain the patency of the airways during exhalation so that mucus does not become trapped as it moves up the airways); and (3) accelerate expiratory airflow (which facilitates the upward movement of mucus through the airways so that it can be more easily cleared).	The principle of the AirPhysio as a mucus clearance device is its ability to: (1) vibrate the airways (which loosens mucus from airway walls); (2) intermittently increase endobronchial pressure (maintains patency during exhalation). (3) The moveable stainless-steel ball inside the device opposes the patient's exhalation which creates a resistance due to the weight of the ball. During exhalation, the force of gravity on the ball and the pressure of the exhaled air causes the ball to vibrate (bounce) up and down. (4) This cycle repeats itself throughout each exhalation. (5) During the exhalation, the positive expiratory pressure (PEP) combined with the vibrations of the rapidly oscillating steel ball, helps to loosen mucus and mobilise secretions from the airways to the throat for expectoration.
Substantial Equivalence Discussion	The principles of operation in both the predicate and subject devices focus on generating positive expiratory pressure (PEP) with a moveable steel ball that opposes a patient's exhalation. PEP is created in the same way in both devices. The force of gravity on the ball and the pressure of the patient's exhaled air causes the ball to vibrate up and down rapidly, helping to loosens mucus and mobilise secretions. This principle, known as oscillating high frequency PEP (OPEP) combine both PEP and airway oscillation techniques and is the technological principle being employed in both the subject and predicate devices.	

	PREDICATE DEVICE - Flutter D	**SUBJECT DEVICE - AirPhysio**
Contraindications	The FLUTTER® is contraindicated for patients known to have pneumothorax or overt right-sided heart failure. FLUTTER should Not be used by patients with the following conditions:- • pneumothorax • severe tuberculosis • right-sided heart failure • haemoptysis (coughing-up blood)	AirPhysio is contraindicated for patients known to have: • Pneumothorax • Tuberculosis • Haemoptysis (coughing up blood) • Oesophageal surgery • Right-sided heart failure • Middle ear pathology (i.e. ruptured tympanic membrane)
Environment of Use	Home / Healthcare facility	Home / Healthcare facility
Material of Use / Duration contact	Polypropylene, stainless steel / <24 hours	Polycarbonate, stainless steel / <24 hours
Contacting Component	Mouthpiece of body made from Polypropylene	Mouthpiece of body made from Polycarbonate
Power Source	Exhalation- Manual, mechanical powered device	Exhalation- Manual, mechanical powered device
OTC / Prescriptive	Prescriptive	Prescriptive
Substantial Equivalence Discussion	Both subject and predicate devices have the same contraindications, made from similar plastic materials, same power source and having the same patient contacting component.	

Performance Data

Biocompatibility evaluation for AirPhysio device was conducted on 9 complete assemblies and in accordance with the FDA Use of International Standard ISO 10993-1. The studies concluded that the test article was not considered to have any cytotoxic effects, did not elicit any sensitization reactions and based on erythema and edema scores, no irritations were observed.

The subject device is considered:

- Contact type: Surface device (exhalation only)
- Contact Duration: A - Permanent Exposure (>30 days)

In support of the reprocessing guidelines, independent laboratory tests verified that when followed, the AirPhysio is sufficiently clean, hygienic and as safe to use as the legally marketed predicate device.

AirPhysio conducted comparative bench testing to assess the performance characteristics of the AirPhysio device with the legally marketed predicate across different flow rates. The following performance measures were compared a) Mean PEP, b) Peak PEP, c) Amplitude PEP, d) Oscillation Frequency Comparison. A Bland Altman Analysis was performed to further support the equivalence of the performance measures. The results showed that the AirPhysio and predicate device have comparable characteristics and substantially similar output specifications.

AirPhysio also undertook usability testing to demonstrate that the use of the device in the target user population and environment was safe, and that a patient's interaction with the device did

not pose any adverse risks. AirPhysio's human factors validation testing followed FDA's human factors guidance document, *Applying Human Factors and Usability Engineering to Medical Devices (Feb 3, 2016).* Based on the findings of the study, it was concluded that the AirPhysio device is as safe and effective for the intended use, its users and the user environments as the predicate device.

Substantial Equivalence

The AirPhysio device is substantially equivalent to the predicate device Flutter D (K972859).

The conclusions drawn from our reviews demonstrate that the subject, AirPhysio device is as effective and performs as well as the legally marketed predicate device.

The subject device has the same intended use as the predicate, operates on the same technological principles and has the same technological characteristics in design and is as safe to use as the predicate device.

Performance data demonstrates that the AirPhysio is substantially equivalent to the predicate device across a range of performance measures.