March 31, 2021

Respinova Ltd.
% Joel Ironstone
President
Ironstone Product Development Inc.
250 Carlaw Avenue, Suite 108
Toronto, Ontario M4M 3L1
Canada

Re: K203378
Trade/Device Name: Pulsehaler
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive Spirometer
Regulatory Class: Class II
Product Code: BWF
Dated: February 15, 2021
Received: February 22, 2021

Dear Joel Ironstone:

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)*

K203378

Device Name

Pulsehaler™

Indications for Use *(Describe)*

Pulsehaler™ is indicated for use as a Positive Expiratory Pressure (PEP) Device.

- The use of Pulsehaler™ improves clearance of secretions
- The use of Pulsehaler™ may reduce the need for postural drainage
- Pulsehaler™ facilitates opening of airways in patients
- Pulsehaler™ may be used to prevent or reverse atelectasis
- Pulsehaler™ may also be useful in the removal of mucus from the lungs

Pulsehaler™ is intended for single patient, adult users in a home or hospital environment.

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

Respinova's Pulsehaler™

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Respinova Ltd.
8 Hachoshlim St.
Herzliya, Israel 4672408
Phone: 1-416-567-1147

Contact Person:
Joel Ironstone
250 Carlaw Avenue, Suite 108
Toronto, ON, Canada
M4M 3L1
1-416-567-1147

Date Prepared: March 30, 2021

Name of Device

Pulsehaler™

Device Classification and Product Code

Spirometer, Therapeutic (Incentive), 21 CFR 868.5690, Class II, BWF

Predicate Devices

Actegy - Aerosure Medic (K140772, Predicate Device)
Trudell Medical - Aerobika (K123400, Reference Device)

Indications for Use

Pulsehaler™ is indicated for use as a Positive Expiratory Pressure (PEP) Device.

- The use of Pulsehaler™ improves clearance of secretions
- The use of Pulsehaler™ may reduce the need for postural drainage
- Pulsehaler™ facilitates opening of airways in patients
- Pulsehaler™ may be used to prevent or reverse atelectasis
- Pulsehaler™ may also be useful in the removal of mucus from the lungs

Pulsehaler™ is intended for single patient, adult users in a home or hospital environment.

Pulsehaler™ is a prescription device.

Device Description

Pulsehaler™ is a non-invasive handheld treatment device used daily by the patient to promote airway opening and secretion clearance by vibrating the air in the airways at a variety of different frequencies. It consists of Base Unit with an LCD touch screen that provides a pressure source, and a Hand Unit with a rotating disc that periodically interrupts the pressure source to deliver pressure pulsations to the patient. These components are connected by an air hose and an electrical power and data cable.

While sitting in a relaxed position, the patient holds the Hand Unit and breathes normally through its mouthpiece. A steady flow of pressurized air is delivered to the Hand Unit component by the Base Unit and enters the air inlet of the Hand Unit. The pressurized air passes along the internal airflow duct of the Hand Unit through an air filter until it reaches the rotating disc. When it rotates the disc interrupts the continuous flow of air from the Base Unit and then releases the flow in pulses at a rate corresponding to the rotation speed. The rotation speed of the disc is determined by the software using a pre-set protocol.

The exhalation port is restricted in size, which together with the positive pressure generated by the Base Unit, induces PEP.

The patient is treated with the device for 20 minutes at a time, up to three times a day according to the prescribing physician's instructions. During each 20-minute treatment, Pulsehaler™ delivers pulses varying from 5 to 50 pulses per second. The patient may use the User Interface to pause the treatment at any time or resume after a pause.

Pulsehaler™ is intended for single adult patient, multiple reuse, at home or in a healthcare facility and is non-sterile. The instructions for use contain cleaning and high-level disinfection instructions that involve the use of Cidex.

Expected Use Life of the device is 5 years and Shelf Life is 6 Months.

Summary of Non-Clinical Testing

Non-Clinical testing included the following on the subject device:

- Positive Expiratory Pressure (PEP) characterization and comparison to the predicate device
- Characterization of the pressure pulse frequencies and pressure pulse amplitudes, and comparison to the predicate device
- Cleaning and Disinfection Validation
- Shelf Life (6 Months) and Use Life (5 years) Testing
- Functional Testing and Software Validation to Design Input Requirements
- Biocompatibility Testing including Volatile Organic Compound (VOC) and Particulate Matter 2.5 Micron Testing - External Communicating, tissue / bone / dentin and Surface contact, Mucosal Membrane, permanent contact duration.

Standards Compliance

The Pulsehaler has been tested to be compliant with the following FDA recognized standards:

- Electrical safety testing per IEC 60601-1:2005 (Third Edition) + C1:2006 + C2:2007 + A1:2012
- Electromagnetic compatibility per IEC 60601-1-2:2014 (4th Edition)
- Usability testing per IEC 60601-1-6:2013 (Edition 3.1)
- Home healthcare environment testing per IEC 60601-1-11:2015 (2nd Edition)
- Biocompatibility testing per ISO 10993 suite and ISO 18562-3:2002 (1st Edition)
- Software development per IEC 62304:2006
- Software validation per FDA's *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices* (May 11, 2005)

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.". The software level of concern was moderate.

Comparison of Technological Characteristics with the Predicate Device

The Pulsehaler™ is substantially equivalent to the Aerosure (K140772). The Pulsehaler™ has the same intended use and indications for use as its predicate device, as well as similar technological characteristics and principles of operation as its predicate device. Both the Pulsehaler™ and the Aerosure deliver vibrating air pressure pulses into the airway to assist in secretion clearance and airway opening. In both devices, air pulses are created by the interruption of the flow of air to and from the patient by a spinning disc.

Both systems apply intermittent pulsating pressure to lung airways. Pulsehaler has similar vibration frequencies and similar levels of positive expiratory pressure (PEP) to its predicate and reference devices.

A summary of substantial equivalence comparison is provided below.

Substantial Equivalence Table

Characteristic	Pulsehaler™	Aerosure (K140772) Predicate Device	Aerobika (K123400) Reference Device	Comparison
Indications for Use	Pulsehaler™ is indicated for use as a Positive Expiratory Pressure (PEP) Device. • The use of Pulsehaler™ improves clearance of secretions • The use of Pulsehaler™ may reduce the need for postural drainage • Pulsehaler™ facilitates opening of airways in patients • Pulsehaler™ may be used to prevent or reverse atelectasis • Pulsehaler™ may also be useful in the removal of mucus from the lungs Pulsehaler™ is intended for single patient, adult users in a home or hospital environment.	Aerosure is indicated for use as a Positive Expiratory Pressure (PEP) Device. • The use of Aerosure improves clearance of secretions • The use of Aerosure may reduce the need for postural drainage • Aerosure facilitates opening of airways in patients with Cystic Fibrosis, COPD, asthma, and lung diseases with secretory problems • Aerosure may be used to prevent or reverse atelectasis • Aerosure may also be useful in the removal of mucus from the lungs of patients who have chronic bronchitis or bronchiectasis	The Aerobika* Oscillating Positive Expiratory Pressure device is intended for use as a Positive Expiratory Pressure (PEP device. The Aerobika* Oscillating PEP device may also be used simultaneously with nebulized aerosol drug delivery. The device is intended to be used by patients capable of generating an exhalation flow of 10 lpm for 3-4 seconds.	Same as predicate
Intended Use Environment	Hospital and Home Use	Hospital and Home Use	Hospital and Home Use	Same as predicate
Patient Population	Adult patients	Patients age 21 and above with Cystic Fibrosis, COPD, asthma, and lung diseases with secretory problems, and patients with atelectasis.	Patients capable of generating and exhalation flow of 10 l pm for 3-4 seconds.	Similar to predicate, no specific disease conditions are claimed.
Oscillation Mechanism	Rotating Disc	Rotating Disk	Oscillating Lever	Same as predicate

Characteristic	Pulsehaler™	Aerosure (K140772) Predicate Device	Aerobika (K123400) Reference Device	Comparison
PEP Mechanism	Flow vs resistance from oscillation mechanism, restricted orifice, and blower	Flow vs resistance from oscillation mechanism, restricted orifice	Flow vs resistance from oscillation mechanism, restricted orifice, and blower	Subject device generates PEP with a blower, however, output PEP pressures, vibration frequencies and amplitudes are equivalent to those produced by predicate and reference device.
Operating Modes	Single mode with multiple speeds	Single Speed Mode	5 levels of resistance	Subject device has multiple speeds. Output PEP pressures, vibration frequencies and amplitudes produced at each speed are equivalent.
Software Control	Yes	Yes	No	Same as predicate
Mean Frequency	6 Hz to 65Hz	30 Hz-52Hz	7Hz- 22Hz	Mean frequencies generated by subject device are within the range generated by predicate and reference device.
Pressure Amplitude	9-23 cmH2O	2-32 cmH2O	1-21 cmH2O	Pressure amplitude generated by subject device is within the range generated by predicate and reference device.
Mean Pressure	7-10 cmH2O	1-11 cmH2O	1-25 cmH2O	Mean pressure generated by subject device is within the range generated by predicate.
Pressure Limitation	Based on hardware blower limitations	Limited by patient's respiratory effort	Limited by patient's respiratory effort	Output pressure of blower limited during single and multiple faults to <20cmH_2O
Power Supply	AC Mains connected DC power supply, 110~240V 50/60Hz	Charger: AC mains connected DC power supply, 110~240 V / 50/60Hz Hand Unit: 3 cell NiMH rechargeable battery (nominal 3.6V).	None (mechanical device)	Wall power to Base Unit – same as predicate; however, Hand Unit is connected and powered by Base Unit, instead of rechargeable batteries
Sterility	Used non-sterile	Used non-sterile	Used non-sterile	Same as predicate

Characteristic	Pulsehaler™	Aerosure (K140772) Predicate Device	Aerobika (K123400) Reference Device	Comparison
Standards with which the Device Complies	ISO 10993; IEC 60601-1-2; IEC 60601-1, IEC 60601-1-6, IEC 60601-1-11, ISO18562	ISO 10993; IEC 60601-1-2; IEC 60601-1	ISO 10993	Additional applicable standards met

Conclusions

The Pulsehaler™ has the same intended use, indications for use, and similar technological characteristics as its predicate device. Testing demonstrates substantially equivalent performance to the predicate device. Therefore, the Pulsehaler™ is substantially equivalent to its predicate.