DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 25, 2016

Medica Holdings, LLC
c/o Paul Dryden
Regulatory Consultant for Medica Holdings, LLC
5200 Meadows Road, Suite 150
Lake Oswego, Oregon 97035

Re: K153441
Trade/Device Name: VibraPEP™
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive Spirometer
Regulatory Class: Class II
Product Code: BWF
Dated: February 22, 2016
Received: February 23, 2016

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K153441

Device Name

VibraPEP™

Indications for Use *(Describe)*

The VibraPEP™ Mucus Clearing Device is a Positive Expiratory Pressure, PEP Device. It was designed to exercise patient's lungs and to improve secretion clearance.

Patient – Patients who have been prescribed PEP therapy

Environment – Hospital, clinics, physician offices, home setting

Type of Use *(Select one or both, as applicable)*

XX 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
March 15, 2016

Date Prepared March 15, 2016

Official Contact:
George Reed
Medica Holdings, LLC
5200 Meadows Road, Suite 150
Lake Oswego, OR 97035
Tel – 503-227-1900

Proprietary or Trade Name: VibraPEP™

Common/Usual Name: Spirometer, Therapeutic (Incentive)

Classification Name: BWF – 21CFR868.5690, Class II

Predicate Device: Pari – RC-Cornet – K983308

Device Description:
The VibraPEP™ is a Positive End Expiratory (PEP) device in which the user exhales through the device and the device generates expiratory pressure (resistance) and the Tube Valve oscillates creates a range of frequencies within the air column to the patient which help to promote secretion clearance. The VibraPEP™ has been designed to be very similar to the predicate RC-Cornet device (K983308). The basic design, form, function and performance have been compared to the predicate and have been demonstrated to be functionally equivalent and with the same intended use as the predicate.

The device is comprised of several components:
- Curved tube
- Cap for end of Tube
- Mouthpiece with selector
- Valve tube
- Drying tool

Principle of Operation
The VibraPEP™ is a curved tube in which a long valve is inserted. As the patient blows through the VibraPEP, the hose pressure increases and buckles at the bending of the tube. When the peak pressure is reached, the hose end opens and is catapulted against the wall releasing its pressure. This process is repeated, providing an oscillation effect during the entire exhalation phase. By rotating the therapy selector, pressure and flow can be adjusted to increase or decrease the pressure and frequency of PEP therapy.

Indications for Use:
The VibraPEP™ Mucus Clearing Device is a Positive Expiratory Pressure, PEP Device. It was designed to exercise patient's lungs and to improve secretion clearance.

Patient – Patients who have been prescribed PEP therapy

Environment – Hospital, clinics, physician offices, home setting

Contraindications:
Although no absolute contraindications to the use of PEP Therapy have been reported, the following should be carefully evaluated before a decision is made to initiate therapy:

- Inability to tolerate increased work of breathing
- Hemodynamic instability
- Intracranial pressure (IPC) > 20 mm Hg
- Acute sinusitis
- Recent facial, oral or skull surgery or trauma
- Epistaxis
- Esophageal surgery
- Active hemoptysis
- Untreated pneumothorax
- Nausea
- Known or suspected tympanic membrane rupture or other middle ear pathology

Substantial Equivalence

Features	Predicate - RC-Cornet K983308	Proposed VibraPEP™
Indications for use	The PARI RC Cornet Mucus Clearing Device is a Positive Expiratory Pressure PEP Device and it was designed to exercise patient's lungs and to improve secretion clearance. The device was designed to work with PARI LC Nebulizers.	The VibraPEP™ Mucus Clearing Device is a Positive Expiratory Pressure, PEP Device. It was designed to exercise patient's lungs and to improve secretion clearance.
Environment of Use	Hospital, clinics, physician offices, home setting	Hospital, clinics, physician offices, home setting
Patient Population	General population	Patients who have been prescribed PEP therapy
Contraindications	• Hemodynamic instability • Intracranial pressure (IPC) > 20 mm Hg • Acute sinusitis • Recent facial, oral or skull surgery or trauma • Epistaxis • Esophageal surgery • Active hemoptysis • Untreated pneumothorax • Nausea • Known or suspected tympanic membrane rupture or other middle ear pathology	• Hemodynamic instability • Intracranial pressure (IPC) > 20 mm Hg • Acute sinusitis • Recent facial, oral or skull surgery or trauma • Epistaxis • Esophageal surgery • Active hemoptysis • Untreated pneumothorax • Nausea • Known or suspected tympanic membrane rupture or other middle ear pathology
Principle of Operation	Tube valve that upon patient exhalation will create PEP and oscillation Adjustable to create different frequencies	Tube valve that upon patient exhalation will create PEP and oscillation Adjustable to create different frequencies

Features	Predicate - RC-Cornet K983308			Proposed VibraPEP™		
Use with a nebulizer	Pari LC nebulizer			No recommendation		
Single patient, multi-use	Yes			Yes		
Cleaning method	Soap / water and Boiling water			Soap / water and Boiling water		
Components that may be used	Not specified Tee adapter to be inserted between nebulizer and mouthpiece Pari LC nebulizers			No user supplied components		
Components	Curved tube Mouthpiece / selector Tube Valve Cap Drying device			Curved tube Mouthpiece / selector Tube Valve Cap Drying device		
Performance – Non-clinical						
Materials per ISO 10993	Surface Contact Mucosal membrane Duration of Use – permanent (> 30 days)			Surface Contact Mucosal membrane Duration of Use – permanent (> 30 days) Identical materials - K983308		
	Flow rate			Flow rate		
	10 lpm	20 lpm	40 lpm	10 lpm	20 lpm	40 lpm
Ave. Pressure (cmH_2O) across full range	11 – 14	17 – 21	23 – 44	10 – 13	18 – 21	27 - 41
Ave. Pressure Amplitude (cmH_2O) across full range	6 – 19	21 – 27	46 – 80	7 – 17	22 – 28	51 - 76
Ave. Flow Rate (lpm) across full range	6 - 16	12 – 18	15 - 21	8 - 16	12 – 17	19 -22

Note: The pressure, frequency and flow testing was performed on the bench at a constant flow rate for comparative purposes.

Discussion of Substantial Equivalence

The VibraPEP™ oscillator PEP device is viewed as substantially equivalent to the predicate device because:

Indications for Use –
The proposed indications for use are to exercise patient's lungs and to improve secretion clearance. **Discussion -** The indications for use are similar for the proposed device and the predicate – K983308 – RC-Cornet. The use with a nebulizer is not included.

Patient Population –
The patient population has been clarified to be for patients who have been prescribed PEP therapy.
Discussion - The patient population is intended to be identical to the predicate device, however the predicate did not specify a patient population other than to imply general patient population. The proposed language is viewed as substantially equivalent with added clarification vs. the predicate – K983308 – RC-Cornet.

Environment of Use –
The proposed environments of use are Hospital, clinics, physician offices, home setting.
Discussion – The environment of use is identical for the proposed device and the predicate – K983308 – RC-Cornet.

Technology –
The design as a curved tube with mouthpiece/selector, tube valve and cap is the identical principle of operation.
Discussion – The technology for generating oscillation and expiratory pressure is identical to the predicate – K983308 – RC-Cornet.

Non-clinical Testing

Materials –
The materials in patient contact and the gas pathway are identical to the predicate – RC-Cornet, K983308. We have evaluated the materials and their type of relations to the patient and determined that they are characterized as:

- Surface Contact
- Mucosal membrane
- Duration of Use – permanent (> 30 days)

Discussion - We have been supplied identification of the materials used by the predicate. We have selected the identical materials and certify that the manufacturing processes are identical for the proposed device and the predicate K983308 – RC-Cornet. We provided Material Certifications with the predicate which has the identical indications for use, patient population, environment of use, type of patient contact.

Comparative Bench Testing
We performed a number of performance tests which included:

- Comparative Performance at 10, 20, and 40 lpm
    - Average Pressure
    - Average Pressure Amplitude
    - Frequency
    - Average Flow Rate
- Cleaning validation
- Age testing
- Mechanical / Drop test

The comparative bench testing demonstrated that the VibraPEP™ is equivalent to the predicate K983308 – RC-Cornet. See **Table 1** above.

The comparative testing demonstrates that the proposed device is substantially equivalent to the predicate device.

Discussion of Differences and Substantial Equivalence Conclusion

As detailed above, the indications for use, patient population, environment of use, technology or principle of operation, and performance have been demonstrated to be substantially equivalent to the predicate.

There are no differences between the proposed VibraPEP™ and the predicate – K983308 – RC-Cornet and based upon the comparative performance testing we can conclude that there are no new safety or effectiveness concerns and thus can determine then to be substantially equivalent.