DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 21, 2017

Medica Holdings, LLC
% Paul Dryden
Consultant
Promedic, LLC
24301 Woodsage Dr.
Bonita Springs, Florida 34134

Re: K163091
Trade/Device Name: VibraPEP™
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive Spirometer
Regulatory Class: II
Product Code: BWF
Dated: January 15, 2017
Received: January 17, 2017

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,

Tina Kiang, Ph.D.
Acting 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)*

K163091

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. The device may be connected via a Valved T-adapter for use with a jet nebulizer for aerosol drug delivery. The VibraPEP™ Mucus Clearing Device is not intended to be used while connected to a jet nebulizer which is delivering nebulized steroidal drugs or antibiotics.

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.

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Date Prepared	February 21, 2017
Official Contact:	George Reed Medica Holdings, LLC 5200 Meadows Road, Suite 150 Lake Oswego, OR 97035 Tel – 503-223-5360
Proprietary or Trade Name:	VibraPEP™
Common/Usual Name:	Spirometer, Therapeutic (Incentive)
Classification Name:	BWF – 21CFR868.5690, Class II
Predicate Device:	Pari / Medica Holdings – RC-Cornet – K983308
Reference Device:	Medica Holdings – VibraPEP™ - K153441

Device Description:
The proposed device is the identical VibraPEP™ cleared under K153441 but with a Valved T-adapter and mouthpiece that allow the user to connect a general purpose jet nebulizer.

The VibraPEP™ is an Oscillatory PEP (OPEP) device that looks like a curved shaped pipe with a plastic mouthpiece at one end. A long hose is attached inside. 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 with pressure during the exhalation phase. By rotating the therapy selector, pressure and flow can be adjusted to achieve optimal therapy for each patient. The VibraPEP™ facilitates mucus clearing by generating and delivering an oscillation effect that vibrates the airways and lung secretions, causing lung secretions to thin and become expelled.

Device Description:
The VibraPEP™ is similar to the predicate RC-Cornet device, cleared on K983308. It has been demonstrated to be functionally equivalent and with the same intended use to the predicate.

The primary device is comprised of several components:

- Curved tube
- Cap for end of Tube
- Mouthpiece with selector
- Valve tube
- Drying tool
- Valved T-adapter for use to connect a general purpose nebulizer

The VibraPEP can allow the patient to connect a standard jet nebulizer via a “tee” adapter and during inhalation receive an aerosol treatment, but with a one-way valve, upon exhalation the user exhales through the VibraPEP™ device to PEP therapy.

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.

The modification in this submission is the addition of a Valved T-adapter which allows one to connect a general purpose nebulizer and the VibraPEP™ together. Due to the directional valve in the Valved T-adapter, a patient during inhalation would inhale the aerosolized medications from the nebulizer and during exhalation the valve prevent flow back to the nebulizer and the patient then exhaled through the VibraPEP™. It is the same as if the patient used the 2 devices separately.

Compatibility with aerosolized medications:
Medications which open your airways or help to thin mucus would be good choices to use with your VibraPEP™ Oscillating PEP because they would help remove or thin the mucus in your lungs.

Medications you want to stay in your lungs, like antibiotics and steroids, should be taken after you have completed your VibraPEP™ Oscillating PEP treatment.

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. The device may be connected via a Valved T-adapter for use with a jet nebulizer for aerosol drug delivery. The VibraPEP™ Mucus Clearing Device is not intended to be used while connected to a jet nebulizer which is delivering nebulized steroidal drugs or antibiotics.

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

Substantial Equivalence
The following tables present the comparison and then we discuss the differences.

Table 1 – Comparison Predicate and Reference to Proposed Device

Features	Predicate RC-Cornet K983308	Reference VibraPEP™ K153441	Proposed VibraPEP™ with Valved T-adapter
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.	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. The device may be connected via a Valved T-adapter for use with a jet nebulizer for aerosol drug delivery.
Environment of Use	Hospital, clinics, physician offices, home setting	Hospital, clinics, physician offices, home setting	Hospital, clinics, physician offices, home setting
Patient Population	Children 4 years and older to adults	Patients who have been prescribed PEP Therapy	Patients who have been prescribed PEP Therapy
Contraindications	- Intracranial pressure (IPC) > 20 mm Hg - Hemodynamic instability - Recent facial, oral or skull surgery or trauma - Acute sinusitis - Epistaxis - Esophageal surgery - Active hemoptysis - Untreated pneumothorax - Nausea - Known or suspected tympanic membrane rupture or other middle ear pathology	- Intracranial pressure (IPC) > 20 mm Hg - Hemodynamic instability - Recent facial, oral or skull surgery or trauma - Acute sinusitis - Epistaxis - Esophageal surgery - Active hemoptysis - Untreated pneumothorax - Nausea - Known or suspected tympanic membrane rupture or other middle ear pathology - Patients unable to tolerate the increased work of breathing (acute asthma, COPD)	- Intracranial pressure (IPC) > 20 mm Hg - Hemodynamic instability - Recent facial, oral or skull surgery or trauma - Acute sinusitis - Epistaxis - Esophageal surgery - Active hemoptysis - Untreated pneumothorax - Nausea - Known or suspected tympanic membrane rupture or other middle ear pathology - Patients unable to tolerate the increased work of breathing (acute asthma, COPD)
Principle of Operation (PEP)	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	Tube valve that upon patient exhalation will create PEP and oscillation Adjustable to create different frequencies

Features	Predicate RC-Cornet K983308	Reference VibraPEP™ K153441	Proposed VibraPEP™ with Valved T-adapter
Use with a nebulizer	Use of a Valved T-adapter to connect the outlet of the nebulizer	No	Use of a Valved T-adapter to connect the outlet of the nebulizer
Specified Nebulizer	Pari LC	None	General Purpose small volume nebulizers
Duration of Use	Single patient, multi-use	Single patient, multi-use	Single patient, multi-use
Cleaning method	Soap / water Boiling water	Soap / water Boiling water	Soap / water Boiling water
Accessories	Valved – T-adapter to be inserted between nebulizer and mouthpiece Pari LC nebulizers	None	Valved T- adapter to be inserted between nebulizer and mouthpiece User supplied cleared jet nebulizer
Components	Curved tube Mouthpiece / selector Tube Valve Cap Drying device T-adapter	Curved tube Mouthpiece / selector Tube Valve Cap Drying device	Curved tube Mouthpiece / selector Tube Valve Cap Drying device Valved T-adapter
Biocompatibility **ISO 10993-1**	Surface Contact Mucosal membrane Externally Communicating Tissue Duration of Use – permanent (> 30 days)	Surface Contact Mucosal membrane Duration of Use – permanent (> 30 days)	Surface Contact Mucosal membrane Externally Communicating Tissue Duration of Use – permanent (> 30 days)
			Cytotoxicity Sensitization Irritation Leachable / Extractable 2 solvents Risk Based Assessment
Performance Testing – Non-clinical			
Shelf-life	Not specified	1 year	1 year

Features	**Predicate RC-Cornet K983308**			**Reference VibraPEP™ K153441**			**Proposed VibraPEP™ with Valved T-adapter**		
Performance without the Valved T-adapter Data from K153441 Across Settings 1, 3, and 5									
	Flow Rate			**Flow Rate**			**Flow Rate**		
	10 lpm	20 lpm	40 lpm	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	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	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	8 - 16	12 – 17	19 -22
Performance with Valves T-adapter Across Settings 1, 3, and 5									
Ave. Pressure (cmH_2O) across full range	10 13 15	Setting 1 - 22 Setting 3 - 19 Setting 5 – 19	41 39 30	N/A	N/A	N/A	9 12 13	Setting 1 - 21 Setting 3 - 18 Setting 5 - 18	40 38 29
Ave. Pressure Amplitude (cmH_2O) across full range	5 6 18	Setting 1 - 20 Setting 3 - 21 Setting 5 – 26	60 54 50	N/A	N/A	N/A	5 6 13	Setting 1 - 19 Setting 3 - 19 Setting 5 – 24	58 52 46
Frequency (Hz)	16 15 9	Setting 1 - 17 Setting 3 - 16 Setting 5 - 13	20 21 17				15 15 8	Setting 1 - 17 Setting 3 - 16 Setting 5 - 13	20 21 18
Ave. Flow Rate (lpm) across full range	10 10 10	20	40 40 40	N/A	N/A	N/A	10 10 10	20	40 40 40

Table 2 – Comparison of General Purpose Nebulizer as Standalone vs. Attached to VibraPEP™

Measurement (Mean)	**Standalone configuration**	**With VibraPEP**	**Standalone Configuration**	**With VibraPEP**	**Standalone configuration**	**With VibraPEP**
Westmed - VixOne (K800562)						
	Albuterol		**Cromoly Sodium**		**Ipratropium Bromide**	
MMAD (um)	1.7	1.37	1.67	1.43	1.53	1.37
GSD	2.24	2.21	2.04	1.75	2.11	2.09
Total Dose (ug)	1256	1050	6295	5212	262	252
Total Respirable Dose (0.5-5)	896	790	4939	4106	174	147
Coarse Particle > 4.7	266	154	881	555	72	83
Fine particle (<4.7)	990	896	5413	4657	190	169
Ultra-Fine Particle (<1.0)	347	351	1804	2460	64	69
Statistical analysis Significant differences	No		No		No	
Hudson RCI MicroMist (K930525)						
	Albuterol		**Cromoly Sodium**		**Ipratropium Bromide**	
MMAD (um)	1.77	1.40	1.60	1.43	1.53	1.47
GSD	2.94	2.28	2.69	2.75	2.74	2.83
Total Dose (ug)	863	779	2803	2482	127	119
Total Respirable Dose (0.5-5)	497	493	1696	1556	62	60
Coarse Particle > 4.7	277	193	782	564	52	44
Fine particle (<4.7)	586	586	2022	1918	75	75
Ultra-Fine Particle (<1.0)	231	250	828	878	31	34
Statistical analysis Significant differences	No		No		No	

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. The device may be connected via a Valved T-adapter for simultaneous use with a jet nebulizer for aerosol drug delivery.
Discussion - The indications for use as a PEP device are similar to the predicate K983308 – RC Cornett and the reference K153441 – VibraPEP. For simultaneous use with nebulized aerosol drug delivery, the proposed VibraPEP is similar to the predicate – K983308 – RC-Cornet.
Differences – The proposed VibraPEP has been evaluated using 2 cleared general purpose small volume jet nebulizers for aerosol delivery and the testing has shown that the performance of the nebulizer with or without attachment to the VibraPEP is similar. The predicate does not disclose aerosol performance.

Patient Population – The patient population of those that are prescribed PEP therapy is similar to the reference – K153441 – VibraPEP.

Discussion - The patient population is unchanged compared to the reference – K153441 – VibraPEP.
Differences – There are no differences between the proposed VibraPEP and the reference – K153441 – VibraPEP.

Environment of Use – The proposed environments of use are Hospital, clinics, physician offices, home setting.
Discussion – The environment of use is unchanged compared to the reference – K153441 – VibraPEP.
Differences – There are no differences between the proposed VibraPEP and the reference – K153441 – VibraPEP.

Technology – The technology for delivery PEP therapy is unchanged compared to the reference – K153441 – VibraPEP. The ability to connect a nebulizer in-line that allows the user to inhale the aerosolized drug and then exhale through the PEP device is similar to the predicate – K983308 – RC Cornet. Both devices use an in-line T-adapter.
Discussion – The technology for PEP and connecting the nebulizer are similar for both the predicate – K983308 – RC Cornet and reference - K153441 – VibraPEP.
Differences – There are no differences between the proposed VibraPEP and the reference – K153441 – VibraPEP and predicate – K983308 – RC Cornet which raise different questions of safety and effectiveness.

Accessories – The ability to use a Tee adapter to connect a nebulizer is the same as the predicate – K983308 – RC Cornet.
Discussion – The use of the similarly designed T-adapter and use with nebulizers has been shown to not alter the performance of the nebulizer to aerosol a delivered drug.
Differences – Testing has demonstrated that any differences between the proposed VibraPEP and the reference – K153441 – VibraPEP and predicate – K983308 – RC Cornet related to use with a nebulizer has not raise different questions of safety and effectiveness.

Performance Testing – Non-clinical

Biocompatibility and Materials – The new materials (other components are the same as the predicate) in the gas pathway are only the T-adapter and mouthpiece which have been evaluated per ISO 10993-1. They are characterized as:

- External Communicating (Indirect gas pathway)
- Tissue / Bone / Dentin communicating
- Duration of Use – permanent (> 30 days)

And

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

Discussion - We tested the all components of the VibraPEP including the new components. Testing was performed with final, finished product and was found to be non-reactive. We do not supply the nebulizer, but any nebulizer used has been cleared under 510(k) and use with the VibraPEP does not change its intended use.
Differences – Testing has demonstrated that the proposed VibraPEP meets the ISO 10993 requirements and the proposed materials have not raise different questions of safety and effectiveness.

Comparative Performance

- A series of tests were performed comparing the predicate, reference and subject device

- Across flow rates of 10, 20, and 40 lpm
    - Average Pressure
    - Average Pressure Amplitude
    - Frequency
    - Average Flow Rate

Discussion – We demonstrated that the addition of the Valved T-adapter and mouthpiece do not alter the performance of the VibraPEP™ with the Valved T-adapter as compared to the predicate – K983308 – RC Cornet.

Nebulizer performance – We tested samples of cleared small volume jet nebulizers with 3 drugs with and without connection to the VibraPEP. The results show that there were no statistically significant differences between the performances in all configurations.
Discussion - We have demonstrated that the addition of the T-adapter and mouthpiece do not alter the performance of the nebulizer and thus can be used simultaneously with the VibraPEP as indicated with the predicate – K983308 – RC Cornet, which can be used with its specified nebulizer in the same manner.

PEP performance – We tested samples of the VibraPEP™ with the T-adapter and compared performed to the VibraPEP without T-adapter as well as we compared the predicate RC Cornet and its T-adapter for PEP performance. The results show that there no differences between performance.
Discussion - We have demonstrated that the addition of the T-adapter and mouthpiece do not alter the PEP performance.

Effects of Aging, Cleaning, and Drop testing – We performed testing related to aging and cleaning that included mechanical drop testing of the new components, Valved T-adapter and mouthpiece, and found that they continued to meet their performance specifications.

Differences – Testing has demonstrated when a nebulizer is connected to the proposed VibraPEP the performance of the nebulizer is not significantly changed, thus we can stated that there are no different questions of safety and effectiveness.

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 are substantially equivalent to the predicate.

There are no differences between the proposed VibraPEP™ and the predicate – K983308 – RC-Cornet and reference – K153441 - VibraPEP based upon the comparative performance testing which raise different questions of safety and effectiveness.