510(k) Summary
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4/15/2012 K121170

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JUL 13 2012

Official Contact: Barrett R. Mitchell– President

Proprietary or Trade Name: RespIn11 Model

Common/Usual Name: Powered Percussor

Classification Name/Code: BYI – Powered Percussor
CFR 868.5 665
Class II

Device: RespIn11

Predicate Device: Advanced Respiratory – The Vest K024309

Device Description:
RespIn11 is a medical device developed for an effective therapy of airway obstruction conditions. The device is made up of a jacket connected to a vibration/pulsation generator where the pulsations are obtained by the pressure differences of a multistage blower. These pulsations are transmitted to the subject's chest through an air pressure piston system specially designed and inserted into the front and rear cavities of the vest provided. The compression then release cycle on the chest wall generates a differential air speed in the bronchial airway in the lungs. This produces a shearing effect which pulls the mucus off the bronchial airway walls and to then be moved through mucociliary action into the larger upper airways to then be eliminated naturally through coughing or if necessary by external suction. This respiratory therapy is called HFCWO (High Frequency Chest Wall Oscillation).

Indications for Use:
The RespIn11 is intended to provide airway clearance therapy when external manipulation of the thorax is the physician's choice of treatment. Indications for this form of therapy are described by the American Association for Respiratory Care (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy' (1991). According to AARC guidelines, specific indications for external manipulation of the thorax include evidence or a suggestion of retained secretions, evidence that the patient is having difficulty with the secretion clearance, or presence of atelectasis caused by mucus plugging. In addition, the RespIn11 is also indicated for external manipulation of the

thorax to promote airway clearance or improve bronchial drainage for purposes of collecting mucus for diagnostic evaluation.

Environment of Use:
Hospital, sub-intensive, clinical offices, home

Contraindications

- Intracranial pressure (ICP) greater than 20 mm Hg
- Recent spinal surgery or acute spinal injury
- Bronchopleural fistula
- Pulmonary edema associated with congestive heart failure
- Large pleural effusions or empyema
- Pulmonary embolism
- Head and/or neck injury that has not yet been stabilized
- Active hemorrhage with hemodynamic instability
- Distended abdomen
- Active or recent gross hemoptysis
- Uncontrolled airway at risk for aspiration such as tube feeding or a recent meal
- Subcutaneous emphysema
- Recent epidural spinal infusion or spinal anesthesia
- Suspected pulmonary tuberculosis
- Lung contusion
- Bronchospasm
- Coagulopathy
- Complaint of chest wall pain
- - Rib fractures, with or without flail chest (within 30 days – after this may help splint/stabilize)
- Surgical wound or healing tissue or recent skin grafts or flaps on the thorax
- Recent esophageal surgery
- Burns, open wounds, and skin infections on the thorax
- Recent placement of transvenous or subcutaneous pacemaker (within 30 days)

Summary of substantial equivalence

The RespIn11 was compared to the predicate The Vest (K024309) and is presented in the following comparison table.

Table of Comparison

Feature	Respinnovation RespIn11 510(k)	Advanced Respiratory (Hill-Rom) – The Vest 510(k) K024309	Comment
Indications	The RespIn11 is intended to provide airway clearance therapy when external manipulation of the thorax is the physician's choice of treatment. Indications for this form of therapy are described by the American Association for Respiratory Care (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy' (1991). According to AARC guidelines, specific indications for external manipulation of the thorax include evidence or a suggestion of retained secretions, evidence that the patient is having difficulty with the secretion clearance, or presence of atelectasis caused by mucus plugging. In addition, the RespIn11 is also indicated for external manipulation of the thorax to promote airway clearance or improve bronchial drainage for purposes of collecting mucus for diagnostic evaluation.	The intended use of the Modified Vest™ Airway Clearance System is the same as the predicate device, which is to provide airway clearance therapy when external manipulation of the thorax is the physician's choice of treatment. Indications for this form of therapy are described by the American Association for Respiratory Care (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy' (199 1). According to AARC guidelines, specific indications for external manipulation of the thorax include evidence or a suggestion of retained secretions, evidence that the patient is having difficulty with the secretion clearance, or presence of atelectasis caused by mucus plugging. In addition, the VestTM Airway Clearance System is also indicated for external manipulation of the thorax to promote airway clearance or improve bronchial drainage for purposes of collecting mucus for diagnostic evaluation.	Equivalent
Prescriptive	Yes	Yes	Identical

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Feature	Respinnovation RespIn11 510(k)	Advanced Respiratory (Hill-Rom) – The Vest 510(k) K024309	Comment
Technology	Pneumatic percussor, electronic control	Pneumatic percussor, electronic control	Identical
Environment of Use:	Hospital, sub-intensive, clinical offices, home	Hospital, sub-intensive, clinical offices, home	Identical
Power	100-240 VAC, 50-60 Hz, 4.7 A MAX	100 V AC to 230 V AC, 50 Hz to 60 Hz 3.4 A @ 100 VAC, 2.0 A @ 230 VAC	Equivalent
Standards	IEC 60601-1, IEC 60601-1-2	IEC 60601-1, IEC 60601-1-2	Identical
Alarms	None	None	Identical
Control Unit Interface	Alphanumeric	Alphanumeric	Identical
Performance Frequency	Frequencies between 5 – 20 Hz	Frequencies between 5 – 20	Equivalent
Performance Pressure	Pressure applied in 0-10 steps (*max pressure = 50 mbar)	Pressure applied in 0-10 steps (*max pressure = 50 mbar)	Identical
Performance Therapy Times	Session therapy from 5 to 30 minutes depending upon Dr.'s recommendations per patient	From 0 to 60 minutes (* from the Vest User Manual: *common prescription specify a treatment session time to be between 10 and 30 minutes*)	Equivalent
Patient Interface	2 jacket sizes: S/M, L/XXL	4 "vest" styles	Equivalent
Patient Population	Not explicitly limited	Not explicitly limited	Equivalent
Operating Temperature	10°C to 34°C (50°F to 95 °F)	50°F to 93°F (10°C to 34°C) ambient temperature (* from Vest User Manual)	Equivalent

Differences Between Other Legally Marketed Predicate Devices
The RespIn11 is viewed as substantially equivalent to the predicate device because: The percussions provided by the RespIn11 is substantially equivalent to that commonly employed by other powered percussors.

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Prescriptive – The RespIn11 is prescriptive as is the predicate.

Design and Technology – The RespIn11 has equivalent design and features as the predicate and has the identical technology to the predicate.

Performance and Specifications – The RespIn11 has equivalent specifications of performance as the predicate.

Compliance with standards – The RespIn11 and predicate device comply with IEC 60601-1 and IEC 60601-1-2.

Materials –
No patient contact materials

Environment of Use –
RespIn11 is for Hospital, sub-intensive, clinical offices, home, which is similar for predicate.

Patient Population –
RespIn11 is intended for patients that their clinician has determined that this treatment is appropriate. This is similar to the predicate.

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Performance Testing
We have performed performance testing and the results demonstrated that the device performs as intended and is substantially equivalent to the performance of the predicate.

The tests included:

- Frequency Testing
- Pressure Testing
- Pneumatic Testing
- Fault condition testing
- IEC 60601-1 Safety
- IEC 60601-1-2 Electromagnetic Compatibility

The results of the testing demonstrate that the RespIn11 performs equivalent to the predicate.

Conclusion
The RespIn11 has been demonstrated to be substantially equivalent to the predicate, The Vest (K024309), in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

RespInnovation SAS
C/O Mr. Paul Dryden
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

JUL 13 2012

Re: K121170
Trade/Device Name: RespIn11
Regulation Number: 21 CFR 868.5665
Regulation Name: Powered Percussor
Regulatory Class: II
Product Code: BYI
Dated: April 15, 2012
Received: April 17, 2012

Dear Mr. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: _____ (To be assigned)

Device Name: **RespIn11**

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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