DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 7, 2015

Hill-Rom Private Limited
% Mr. Paul Dryden
President
ProMedic Inc.
24301 Woodsage Dr.
Bonita Springs, FL 34134

Re: K142482
Trade/Device Name: The Vest® Airway Clearance System
Regulation Number: 21 CFR 868.5665
Regulation Name: Percussor, Powered-Electric
Regulatory Class: II
Product Code: BYI
Dated: April 3, 2015
Received: April 6, 2015

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 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" (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 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,

Tejashri Purohit-Sheth, M.D.

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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)*

K142482

Device Name

The Vest® Airway Clearance Systems (Model 105)

Indications for Use *(Describe)*

The Vest® Airway Clearance Systems is intended to provide airway clearance therapy when external manipulation of the thorax is the physician's choice or treatment. Indications for this form of therapy are described by the American Association of Respiratory Care (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy. 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 Vest® Airway Clearance System is also indicated for external manipulation of the thorax to promote airway clearance or improve bronchial drainage for the purposes of collecting mucus for diagnostic evaluation.

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 4-May-15

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Proprietary or Trade Name: The Vest® Airway Clearance Systems (Model 105)

Common/Usual Name: Percussor, Powered-Electric

Classification Code/Name: BYI – Powered Percussor
21 CFR 868.5665
Class 2

Predicate Devices: K024309 – The Vest® Airway Clearance System

Device Description:
The Vest® Airway Clearance System consists of an inflatable garment attached to an Air Pulse Generator that rapidly inflates and deflates the inflatable garment. This causes the chest wall to be gently compressed and released, which creates airflow within the lungs. This process moves the mucus toward the large airways where it can be cleared by coughing or suctioning. This type of Airway Clearance Therapy is referred to as High Frequency Chest Wall Oscillation (HFCWO).

The system consists of an Air Pulse Generator, connecting hose, and multiple styles and sizes of garments. The garments are single patient, multi-use.

Indications for Use:
The Vest® Airway Clearance Systems is intended to provide airway clearance therapy when external manipulation of the thorax is the physician's choice or treatment. Indications for this form of therapy are described by the American Association of Respiratory Care (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy. 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 Vest® Airway Clearance System is also indicated for external manipulation of the thorax to promote airway clearance or improve bronchial drainage for the purposes of collecting mucus for diagnostic evaluation.

Patient Population:
The Vest® Airway Clearance System is applicable for a wide variety of settings as recommended by the AARC Guidelines, including: Critical care, in-patient acute care, extended care and skilled

nursing facility care, home care, outpatient / ambulatory care, pulmonary diagnostic (bronchoscopy) laboratory.

The Vest® Airway Clearance System can be used for the pediatric to geriatric population. The system accommodates use across the targeted population by providing a selection of garment sizes which is used along with the Air Pulse Generator.

Predicate Device Comparison:

The Vest® Airway Clearance Systems (Model 105) is substantially equivalent to the predicate device, Vest® Airway Clearance Systems (K024309). We present a summary of the comparison in **Table 1**.

Table 1 – Substantial Equivalence Comparative Table

	Proposed Vest® Airway Clearance System	**Predicate Vest® Airway Clearance System (K024309)**
CFR Classification	868.5665 BYI	868.5665 BYI
Classification name	Percussor, Powered-Electric	Percussor, Powered-Electric
Indications for Use	The Vest® Airway Clearance Systems is intended to provide airway clearance therapy when external manipulation of the thorax is the physician's choice or treatment. Indications for this form of therapy are described by the American Association of Respiratory Care (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy. 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 Vest® Airway Clearance System is also indicated for external manipulation of the thorax to promote airway clearance or improve bronchial drainage for the purposes of collecting mucus for diagnostic evaluation.	The Vest® Airway Clearance Systems is intended to provide airway clearance therapy when external manipulation of the thorax is the physician's choice or treatment. Indications for this form of therapy are described by the American Association of Respiratory Care (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy. 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 Vest® Airway Clearance System is also indicated for external manipulation of the thorax to promote airway clearance or improve bronchial drainage for the purposes of collecting mucus for diagnostic evaluation.

	Proposed Vest® Airway Clearance System	**Predicate Vest® Airway Clearance System (K024309)**
Environments of Use	Critical care, in-patient acute care, extended care and skilled nursing facility care, home care, outpatient / ambulatory care, pulmonary diagnostic (bronchoscopy) laboratory.	Critical care, in-patient acute care, extended care and skilled nursing facility care, home care, outpatient / ambulatory care, pulmonary diagnostic (bronchoscopy) laboratory.
Patient Population	Pediatric to geriatric population	Pediatric to geriatric population
Systems consists of	Air Pulse Generator Connecting hose (60") locking / non-locking Garments of various styles and sizes Chest (permanent) Full Vest (Permanent / SPU / C3) Wrap Vest (Permanent / SPU)	Air Pulse Generator Connecting hose (60-80") non-locking Garments of various styles and sizes Chest (permanent) Full Vest (Permanent / SPU)
Software Modes	Manual (Normal) Bluetooth™ - Yes Operational modes: Programmable Cough Pause® Ramp	Manual (Normal) Operational modes: Manual mode
Electrical Specifications	100 – 230 VAC, 50 / 60 Hz 3.4 A @ 100 VAC / 2.0 A @ 230 VAC Power plug – NEMA 1-15P (2 pin)	100 – 230 VAC, 50 / 60 Hz 5.0 A max Power plug – NEMA 5-15P (3 pin)
Mechanical safety	UL/EN/IEC 60601-1 and CAN/CSA C22.2 No. 601.1	UL/EN/IEC 60601-1 and CAN/CSA C22.2 No. 601.1

Indications –
The proposed indications for use of providing airway clearance therapy when external manipulation of the thorax is the physician's choice or treatment and to promote airway clearance or improve bronchial drainage for the purposes of collecting mucus for diagnostic evaluation.are identical to the predicate.
Discussion: The indications for use are identical to the predicate Vest® Airway Clearance System (K024309).

Technology –
The design of the Vest® Airway Clearance System utilizing an Air Pulse Generator, connecting hose, and inflatable / deflatable garment is unchanged from the predicate.
Discussion: The design is identical with minor modifications to the connecting hose and addition of garment styles, but in all substantially equivalent to the predicate Vest® Airway Clearance System (K024309).

Environment of Use –
The proposed environments of use are Critical care, in-patient acute care, extended care and skilled nursing facility care, home care, outpatient / ambulatory care, pulmonary diagnostic (bronchoscopy) laboratory which are identical to the predicate.
Discussion: The intended environments of use are identical to the predicate Vest® Airway Clearance System (K024309).

Patient Population –
The Vest® Airway Clearance System (K024309) is intended for pediatric to geriatric population.
Discussion: The patient population is identical to the predicate Vest® Airway Clearance System (K024309).

Discussion of Differences –
The basic differences between the proposed device and the predicate are an update in software, addition of styles of garments and addition of a locking style connecting hose. Testing has demonstrated that these differences do not raise any new safety or risks and thus can be found to be substantially equivalent.

Non-clinical Testing Summary -
We performed comparative non-clinical bench testing to demonstrate that the Vest® Airway Clearance System and its modifications and additional garment styles and sizes perform equivalent to the predicate Vest® Airway Clearance System (K024309). These tests included:

- Comparative Pressure mapping of garments with predicate and proposed Air Pulse Generator
- Environmental and Mechanical testing
- ANSI/AAMI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and A2:2010/(R)2012
- 47 CFR FCC Part 15B:2012 (CLASS B)
- IEC 60601-1:2005+CORR,1 (2006) + CORR. 2 (2007)
- EN 60601-1:2006 +CORR: 2010
- CAN/CSA – C22.2 No. 6060101 (2008)
- EN 60601-102: 2007
- ETSI EN 300 328 V1.7.1:2006
- ETSI EN 301 489-1 V1.9.2:2011
- ETSI EN 301 489-17 V2.2.1:2012

Biocompatibility of Materials –
The materials of the garments are not in direct or indirect contact with the patient skin or tissue. The materials are identical to the predicate as well.
Discussion: Biocompatibility testing is not needed.

Substantial Equivalence Conclusion -

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to be substantially equivalent.