Section 5.0 510(k) Summary

DEC 3 1 2012

Administrative Information and Device Identification

Name and address of the manufacturer and sponsor of the 510(k) submission:	Manufacturer: Respironics, Inc. 175 Chastain Meadows Court Kennesaw, GA 30144-3714 Office: (770) 423-2322 Fax: (770) 423-2300 Sponsor: Respironics 1740 Golden Mile Highway Monroeville, PA 15146 Office: 724-387-7562 Fax: 724-387-7490
FDA registration number of the manufacturer of the new device:	Manufacturer: 1040777 (Establishment registration number) Sponsor: 2518422 (Establishment registration number)
Official contact person for all correspondence:	Colleen Witt, RAC Senior Regulatory Affairs Engineer Philips Respironics 1740 Golden Mile Highway Monroeville, PA 15146 Office: 724-387-4870 Fax: 724-387-7490 Email: colleen.witt@philips.com
Date Prepared:	July 16, 2012
Device Name:	Philips Respironics SimplyClear Device
Proprietary name of new device:	Philips Respironics SimplyClear Device
Common or usual name of the device:	Percussor, Powered-Electric
Philips/Respironics model number:	Philips Respironics SimplyClear Device
Classification of new device:	Class II
Classification of the predicate device:	Class II
Classification Panel:	Anesthesiology
Panel Code:	BYI – powered percussor NHJ – noncontinuous ventilator (IPPB)

CFR Regulation Number:	21 CFR 868.5665 a) *Identification.* A powered percussor is a device that is intended to transmit vibration through a patient's chest wall to aid in freeing mucus deposits in the lung in order to improve bronchial drainage and that may be powered by electricity or compressed gas (b) *Classification.* Class II (performance standards).
Predicate Device Name(s) and 510(k) numbers:	Modified Vest Airway™ Clearance System – K024309 Emerson CoughAssist, Model CA-3000 – K002598 Dima Italia Negavent DA-3 Plus Pegaso - K072292 Philips Respironics CoughAssist T70 – K121955
Reason for submission:	New Device

Description of Device:

The Philips Respironics SimplyClear device promotes airway clearance by loosening, mobilizing and clearing secretions. The loosening and mobilization occurs by gradually applying air pulse generated high frequency oscillatory vibrations on the positive and negative pressures applied to the chest wall via the airways. The high frequency oscillatory vibrations release mucus from the bronchial walls, increasing mobilization. The positive to negative shift in pressure produces a high expiratory flow from the lungs, promoting the clearance of the mobilized secretions via coughing.

The SimplyClear device combines the loosening and mobilization functionality of the Vest Airway Clearance System (K024309) with the secretion clearance functionality of the CoughAssist device (K002598), Dima Italia Negavent DA-3 Plus Pegaso (K072292) and the CoughAssist T70 device (K121955).

The key benefits of this device are:

- Oscillations
- Simplicity of Use
  - ➢ Common User Interface across product platforms

  - Triggering adjustments (Cough-Trak)
  - Data storage, transfer and reporting (DirectView and Encore)
- Portability
  - Maintains patient lifestyle
  - Smaller size and decreased weight
- Accessory Options
  - Oximetry Accessory
  - Remote Control Accessory (foot pedal)
  - External Suctioning Accessory Interface
- Power Management Options
  - Detachable battery
  - External DC battery
  - Universal Battery pack

Statement of Intended Use:
The Philips Respironics SimplyClear device assists patients in loosening, mobilizing and clearing secretions by providing high frequency oscillatory vibrations while gradually applying a positive pressure to the airway, then rapidly shifting to a negative pressure. The oscillatory vibrations assist in loosening and mobilizing the secretions while the rapid shift in pressure produces a high expiratory flow rate from the lungs, which promotes the clearance of secretions.

Indications for Use:
The SimplyClear device may be used either with a facemask or mouthpiece, or with an adapter to a patient's endotracheal or tracheostomy tube. It is for use on adult or pediatric patients having difficulty with secretion clearance and/or inability to cough. The SimplyClear device is for use in a hospital, institutional environment or in the home.

Comparison of Device Technological Characteristics to Predicate Device

Substantial Equivalence
The submitted SimplyClear device has the following similarities to the predicate devices listed in this submission which previously received 510(k) concurrence; the SimplyClear device:

- Has the same intended use,
- Uses the same operating principle,
- Incorporates the same basic system requirements including, but not limited to: physical interfaces; modes of operation; therapy controls; and
- Incorporates similar materials
- Is manufactured utilizing the same manufacturing processes

The table below summarizes the key technical characteristics between the SimplyClear device to those of the predicate devices listed in the submission:

Technological Characteristic	**SimplyClear**	**The Vest Airway Clearance System**	**Emerson CoughAssist**	**Negavent DA-3 Plus Pegaso**	**CoughAssist T70**
Patient Population	Adult or pediatric patients having difficulty with secretion clearance and/or inability to cough.	Adult and pediatric patients with evidence or suggestion of retained secretions, evidence that the patient is having difficulty with secretion clearance or presence of atelectasis caused by mucus plugging.	Adult or pediatric patient with an ineffective cough due to muscular dystrophy, myasthenia gravis, poliomyelitis, or other neurologic disorder with some paralysis of the respiratory muscles, such as spinal cord injury.	Adult or pediatric patient unable to cough or clear secretions effectively	Adult or pediatric patient unable to cough or clear secretions effectively
Delivery Type	Non Invasive or Invasive	Non-Invasive , Inflatable Vest	Non Invasive or Invasive	Non Invasive or Invasive	Non Invasive or Invasive
Modes of Operation	Manual and Auto	Auto	Manual and Auto	Manual and Auto	Manual and Auto
Inhalation Pressure	0 to 70 cmH_2O	Pressure setting 1-10	0 to 60 cmH_2O	+5 to 70 cmH_2O	0 to 70 cmH_2O
Exhalation Pressure	0 to -70 cmH_2O	Pressure setting 1-10	0 to -60 cmH_2O	-5 to -70 cmH_2O	0 to -70 cmH_2O
Inhale Flow	Low, Medium, High	N/A	Low and High	Low, Medium, High	Low, Medium, High
Pause Time	0 to 5 seconds	N/A	0 to 5 seconds	0.1 – 9.9 seconds	0 to 5 seconds
Phases of Therapy Cycle	Insufflation, Exsufflation, Pause	N/A	Insufflation, Exsufflation, Pause	Insufflation, Exsufflation, Pause	Insufflation, Exsufflation, Pause
Therapy Features	CoughTrak, Oscillations	Oscillations	N/A	N/A	CoughTrak
Software algorithms including CoughTrak Safety Protocols	Dynamic Stability Analysis Flow and Pressure Based Oscillation Detection Extreme Flow Rate Control and Response Sensor Malfunction Stability	N/A	N/A	N/A	Dynamic Stability Analysis Flow and Pressure Based Oscillation Detection Extreme Flow Rate Control and Response Sensor Malfunction Stability
Oscillations	1 to 20 cmH_2O	N/A	N/A	N/A	N/A

Amplitude					
Oscillation Frequency	0 to 20 Hz	5 to 20 cycles per second (Hz)	N/A	N/A	N/A
Remote Data Access	A secure digital (SD) card provides means for data access		N/A	N/A	A secure digital (SD) card provides means for data access

The table below provides a description of the features of the SimplyClear device that are the subject of this 510(k) submission:

Device Feature	**Description**
User Interface	A new graphical user interface with hierarchal menu system
Delivered Pressure	The device Inhale pressure is 0 to 70 cmH_2O and Exhale pressure is 0 to -70 cmH_2O
CoughTrak	A feature for patients who can provide a spontaneous breathing effort to trigger the cough sequence, instead of using manual or auto modes of therapy. This software feature monitors the device outlet pressure and initiates the Insufflation phase of therapy delivery when the pressure decreases below a set threshold indicative of patient effort.
Oscillations	A feature that delivers an oscillation on the pressure signal based on frequency and amplitude set points
Displayed Therapy Parameters	The device displays outlet pressure, measured peak cough flow and measured inhaled tidal volume
Data Management	Therapy data will be stored on an SD card, which will be compatible with both DirectView and Encore
Oximetry Accessory	Device shall interface with the Oximetry accessory to display current SpO_2 and heart rate data received from the oximeter
Wired Remote Control	A remote control accessory (foot pedal) is provided to initiate manual therapy by means of a wired remote control interface
External Suctioning Accessory Interface	Device shall provide a DC output intended to power an external suctioning accessory
Power Management	Options include a Detachable battery, External DC battery and Universal Battery pack

The software design and algorithm descriptions for each of these features of the SimplyClear device have been provided as part of this 510(k) submission.

Performance Data

Non-Clinical Testing

Black-box performance testing was conducted for the SimplyClear device using side by side bench testing methodologies to demonstrate that the SimplyClear device performs to design input specifications and is equivalent to the predicate devices. This bench testing included both open and closed loop conditions from the defined patient test cases to verify that the SimplyClear software algorithms performed to specification. Bench testing conducted for the SimplyClear device characterized the types of worst case scenario inputs that would be experienced in the intended use environment such as extreme flow rates. Additional white-box

testing verified proper operation under conditions of sensor malfunctions and inaccurate or complete sensor dropout. This combination of testing demonstrated that the SimplyClear devices' closed loop control algorithms function safely and effectively under worst case scenarios.

Device Testing Summary

Verification activities have been performed to verify that the device features stated above did not affect the safety and effectiveness of the subject device. This included bench testing, software unit testing and code reviews. A control system analysis was completed and submitted as part of this 510(k) submission.

The table below provides a summary of the testing that was conducted on the features of the Philips Respironics SimplyClear device that are the subject of this 510(k) submission:

Device Feature	**Testing Summary**
User Interface including displayed therapy parameters	Has been verified to meet product requirements defined for the SimplyClear UI. Bench testing, code reviews and software unit testing was performed to ensure that all display functions, user controls and informational messages performed as intended. The User Interface was verified to ensure that it displayed the proper data and expected therapy information.
Delivered Pressure and Flow Stability	Verification testing has verified that the SimplyClear device delivers accurate pressure for the intended duration of the insufflation, exsufflation and pause phases of therapy. The SimplyClear device has been verified to demonstrate pressure and flow stability across all patient test cases, including extreme flow rates and sensor malfunctions (i.e. sensor inaccuracies and / or complete sensor drop out).
CoughTrak	The CoughTrak feature of the SimplyClear device has been verified to meet product specifications with each defined patient case simulation. The availability, operation and triggering performance has been verified to operate across the range of patient cases.
Oscillations	The Oscillation feature of the SimplyClear device has been verified to meet product specifications. Bench testing at extreme therapy settings has been provided, which includes waveform testing conducted on maximum duration of therapy at extreme therapy settings. Oscillation waveforms were also compared against the predicate device waveforms with no oscillations.
Data Management	Data management of the SimplyClear device has been verified to meet product specifications for SD card data integrity. Software verification, including code reviews and software verification testing was conducted to verify the expected results with the SD card.
Oximetry Accessory	The Oximetry Accessory has been tested to verify the behavior of the pulse oximetry data and the proper display of data received by the oximetry accessory.
Wired Remote Control	Verification testing has been conducted to verify the availability and operation of the SimplyClear wired remote control device.
External Suctioning Accessory Interface	The SimplyClear device has been verified to demonstrate that the device provides power to a suctioning accessory as specified.
Power Management	The SimplyClear device has been verified to properly interface with the

	detachable battery, properly display the battery information, properly charge the battery and indicate a low battery charge. The SimplyClear device has also been verified to be compatible with an external DC power supply, to properly display the power supply information and to properly indicate a low external battery.

Standards Evaluation

This device has been tested to appropriate ISO, ASTM, and IEC standards and other applicable requirements passing all test protocols. The Philips Respironics SimplyClear device was designed and tested according to:

1. ISO 14971 Medical devices – Application of risk management to medical devices

2. ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

3. IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements of Safety

4. IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: Electromagnetic Compatibility

5. IEC 60601-1-6 Medical Electrical Equipment – Part 1-6: Usability

6. IEC 60068 Environmental Testing (Part 2-6, 2-27, 2-64): Mechanical Vibration and Shock Resistance testing

7. IEC 62304 Medical device software – Software life cycle processes

The SimplyClear device complies with the applicable requirements referenced in the FDA guidance documents:

- FDA's Draft Reviewer Guidance for Premarket Notification Submissions - Anesthesiology and Respiratory Devices Branch; Division of Cardiovascular, Respiratory, and Neurological Devices (November 1993); and

- FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005).

As suggested by FDA's November 1993 publication entitled "Reviewer Guidance for Premarket Notification Submissions - Anesthesiology and Respiratory Devices Branch; Division of Cardiovascular, Respiratory, and Neurological Devices" the Philips Respironics SimplyClear device was tested in accordance with the applicable voluntary standards. The Philips Respironics SimplyClear met the required performance criteria and functioned as intended.

Conclusion

The SimplyClear device that is the subject of this 510(k) submission has been validated using non-clinical tests and has been determined to be substantially equivalent to the predicate devices. In summary, bench testing (black-box and white-box) and software code reviews have

confirmed that the SimplyClear device performs equivalently to the cited predicate devices. The indications for use, technological characteristics, and principles of operation are similar to the predicate devices. The Philips Respironics SimplyClear device is substantially equivalent to the predicate devices listed in this summary and the new device does not raise any new issues of safety and effectiveness.

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

December 31, 2012

Ms. Colleen Witt, RAC
Senior Regulatory Affairs Engineer
Respironics
1740 Golden Mile Highway
MONROEVILLE PA 15146

Re: K122111
Trade/Device Name: Phillips Respironics SimplyClear
Regulation Number: 21 CFR 868.5665
Regulation Name: Powered Percussor
Regulatory Class: II
Product Code: BYI, NHJ
Dated: December 28, 2012
Received: December 31, 2012

Dear Ms. Witt:

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,

Kwame O. Ulmer

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

Enclosure

Section 4.0 Indications for Use

Indications for Use

510(k) Number (if known): K122111

Device Name: Philips Respironics SimplyClear

The Philips Respironics SimplyClear device promotes airway clearance by gradually applying air pulse generated high frequency oscillatory vibrations on the positive and negative pressures applied to the chest wall via the airways. The high frequency oscillatory vibrations release mucus from the bronchial walls, increasing mobilization. The shift in pressure produces a high expiratory flow from the lungs, promoting the clearance of the mobilized secretions via coughing.

The Philips Respironics SimplyClear device may be used either with a facemask or mouthpiece, or with an adapter to a patient's endotracheal or tracheostomy tube. It is for use on adult or pediatric patients having difficulty with secretion clearance and/or inability to cough.

The SimplyClear device is for use in a hospital, institutional environment or in the home.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K122111