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

October 16, 2014

Dima Italia Srl
Mr. Dario Basciu
Quality Assurance Responsible
Via Coriolano Vighi, 29
Bologna, ITALY 40133

Re: K140598
Trade/Device Name: Pegaso Cough, Pegaso A-Cough, Pegaso A-Cough Perc
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: NHJ
Dated: July 4, 2014
Received: September 4, 2014

Dear Mr. Basciu,

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 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. 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

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 on last page.

510(k) Number *(if known)*
K140598

Device Name
PEGASO A-COUGH PERC

Indications for Use *(Describe)*
The PEGASO A-COUGH PERC is designed for the use on patients unable to cough or clear secretions effectively due to reduced peak cough expiratory flow, resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease. It may be used either with a facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube.
For use in hospital, institutional setting, or home use given adequate training.
For use on adult patients and pediatric patients 3 years old and up.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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 on last page.

510(k) Number *(if known)*
K140598

Device Name
PEGASO A-COUGH

Indications for Use *(Describe)*
The PEGASO A-COUGH is designed for the use on patients unable to cough or clear secretions effectively due to reduced peak cough expiratory flow, resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease. It may be used either with a facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube. For use in hospital, institutional setting, or home use given adequate training.
For use on adult patients and pediatric patients 3 years old and up.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140598

Device Name
PEGASO COUGH

Indications for Use *(Describe)*
The PEGASO COUGH is designed for the use on patients unable to cough or clear secretions effectively due to reduced peak cough expiratory flow, resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease. It may be used either with a facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube. For use in hospital, institutional setting, or home use given adequate training.
For use on adult patients and pediatric patients 3 years old and up.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

Administrative Information and Device Identification

Name and address of the manufacturer and sponsor of the 510(k) submission	Manufacturer: Dima Italia Srl Via Coriolano Vighi, 29 40133, Bologna – Italy Office: (+39) 051568857 Fax: (+39) 051563994 Sponsor: Dima Italia Srl Via Coriolano Vighi, 29 40133, Bologna – Italy Office: (+39) 051568857 Fax: (+39) 051563994
FDA registration number of the manufacturer of the device:	3007123976 (Facility Registration number)
Official contact person for all correspondence:	Dario Basciu, Senior Regulatory Affairs Engineer Dima Italia Srl Via Coriolano Vighi, 29 40133, Bologna – Italy Office: (+39) 051568857 Fax: (+39) 051563994 Email: tech.support@dimaitalia.com
United States Agent Information	----
Date Prepared:	October 03, 2014
Proprietary Name of new device:	*Pegaso Cough* *Pegaso A-Cough* *Pegaso A-Cough Perc*
Common or usual name of the device:	Secretion Clearance Device
Dima Italia Srl model number:	Pegaso Cough
Classification of new device	Class II
Classification of the predicate device:	Class II
Classification Panel:	Anesthesiology
Panel Code:	NHJ – noncontinuous ventilator (IPPB)

CFR Regulation Number:	21 CFR 868.5905 a) *Identification*. A noncontinuous ventilator (intermittent positive pressure breathing – IPPB) is a device intended to deliver intermittently an aerosol to a patient's lung ot to assist a patient's breathing. b) *Classification*. Class II (performance standards)
Predicate device Name(s) and 510(k) numbers:	Emerson Cough Assist, Model CA-3000 K002598 Dima Italia Negavent DA-3 Plus Pegaso K072292 Philips Respironics CoughAssist T70 K121955 Respironics SimplyClear Percussor K122111
Reason for submission	Device modification.

Description of device.

The Dima Italia Srl *Pegaso Cough* is an electric device useful in clearing retained bronchopulmonary secretions. It acts a "cough" patient simulation, applying a positive air pressure to the airway, then rapidly shifting to a negative air pressure. At the end of this pressure shifting, the *Pegaso Cough* leaves the airways free, at zero pressure, for a pause time determined by operator.

The Inspiratory Flow rising time can be selected on four levels: *Peak, High, Medium, Low*.

This "Forced Insufflation-Exsufflation" is destinated to patients with reduced coughing possibilities due to muscular dystrophy, myasthenia gravis, poliomyelitis respiratory muscles paralysis, such as spinal cord injury. Even patients with other diseases, such emphysema, cystic fibrosis, can be treated with *Pegaso Cough.*

It can be used with a facemask or, with an adapter, to an endotracheal or tracheostomy tube.

The *Pegaso Cough* is realized with a blower, used as pressure and flow generator, and a mechanical valve, commanding the sign and the air pressure intensity outing to the patient.

The blower takes air from atmosphere, and compresses or depresses it in order to generate a positive or negative pressure. The pressure value is controlled by an electronic sensors.

In order to reduce the risks of adverse reactions, an (optional) Masimo oximeter has been added.

An optional flow sensor (trigger) has been added in order to synchronize the inspiration cycles to the first or all the inspiratory efforts of the patient.

An optional high frequency oscillatory vibration (percussion mode) has been added in order to help to clear retained bronchopulmonary secretions.

So, *Pegaso Cough* (without options), *Pegaso A-Cough* (with the trigger option), *Pegaso A-Cough Perc* (with trigger and percussion options) identification names will be used.

Pegaso Cough, Pegaso A-Cough, Pegaso A-Cough Perc are equivalent devices.

The Inspiratory/Expiratory cycles are determined by the blower rotation and the mechanical valve positioning. This valve is connected to a step-motor, whose position is detected through an optical sensor. The valve lets the positive flow go toward the patient and the negative flow toward the atmosphere or, instead, the positive flow to the atmosphere and the negative flow toward the patient.

The working parameters are visualized on a colour TFT display and modified through a touch keyboard.

The settable parameters are:

- Cough assistant modes or Percussion mode (if present)
- Cough Times
- Trigger value (if present)
- Positive Pressure value
- Negative Pressure value
- Percussion Pressure amplitude (if present)
- Percussion Frequency
- Percussion I/E Ratio
- Oximeter configuration and alarms

If the device is in **automatic** mode, the device will continuously cycle, generating an Inspiration phase, followed by an expiration phase, followed by a pause phase.
If the device is in **manual** mode, the device will produce an inspiration phase if the operator moves to the right side the lever of a mechanical switch, will produce an expiration phase if the operator moves the lever to the left, generates a pause phase if the lever is in stand-by position.
When the trigger is present, AutoSync and EasyStart modes are enabled. **Autosync** starts I/E/Pause cycles synchronized with the inspiratory effort of the patient. **Easystart** synchronizes only the first I/E/Pause cycle with the inspiratory effort of the patient. All other cycles will follow the set times as for automatic mode.
When the Percussion option is present, the device enable the **Percussion** mode.
This is a feature that delivers a pressure oscillation based on frequency and amplitude set points.

Statement of Intended Use.
The Dima Italia Srl *Pegaso Cough* assists patients in clearing retained bronchopulmonary secretions by gradually applying a positive pressure to the airway, then rapidly shifting to a negative pressure. This rapid shift in pressure, via a facemask, mouthpiece or an endotracheal or tracheostomy tube, produces a high expiratory flow rate from the lungs, simulating a cough.

Indication for use.

The PEGASO COUGH is designed for the use on patients unable to cough or clear secretions effectively due to reduced peak cough expiratory flow, resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease. It may be used either with a facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube. For use in hospital, institutional setting, or home use given adequate training.
For use on adult patients and pediatric patients 3 years old and up.

Comparison of Device technological Characteristics to predicate device

Substantial Equivalence.

The Dima Italia Srl *Pegaso Cough*, *Pegaso A-Cough*, *Pegaso A-Cough Perc* devices have the following similarities to the previously cleared predicate devices:

- Same intended use
- Same operating principle
- Same technology
- Same manufacturing process

The *Pegaso Cough*, *Pegaso A-Cough*, *Pegaso A-Cough Perc* devices have the secretion clearance functionality substantially equivalent to CoughAssist device (K002598), Dima Italia Negavent DA-3 Plus Pegaso (K072292) and the CoughAssist T70 device (K121955).

The *Pegaso A-Cough Perc* device is useful for the mucus loosening and mobilization. It occurs by applying air pulse generated high frequency oscillatory vibrations on the chest wall via the airways. The high frequency oscillatory vibrations release mucus from the bronchial walls, increasing mobilization.
The *Pegaso A-Cough Perc* device combines the loosening and mobilization functionality of the Philips Respironics SimplyClear (K122111) with the secretion clearance functionality of the CoughAssist device (K002598), Dima Italia Pegaso (K072292) and the CoughAssist T70 device (K121955).

The table below summarizes the key technical characteristics between the *Pegaso Cough* to those of the predicate devices listed in the submission:

Technological Characteristics	**Pegaso Cough Description** K140598	**Pegaso Cough Description** K072292	**Respironics SimplyClear** K122111	**Emerson CoughAssist** K002598	**Philips Respironics CoughAssist T70** K121955
Patient Population	Adult or pediatric patient unable to cough or clear secretions effectively	Adult or pediatric patient unable to cough or clear secretions effectively	Adult or pediatric patients having difficulty with secretion clearance and/or inability to cough	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
Delivery type	Non Invasive or Invasive	Non Invasive or Invasive	Non Invasive or Invasive	Non Invasive or Invasive	Non Invasive or Invasive
Modes of operation	Manual and Auto	Manual and Auto	Manual and Auto	Manual and Auto	Manual and Auto
Inhalation Pressure	0 to 70 cmH_2O	0 to 70 cmH2O	0 to 70 cmH_2O	0 to 60 cmH_2O	0 to 70 cmH_2O
Exhalation Pressure	0 to -70 cmH_2O	0 to -70 cmH2O	0 to -70 cmH_2O	0 to -60 cmH_2O	0 to -70 cmH_2O
Inhale Flow	Low, medium, High, Peak	Low, medium, High	Low, medium, High	Low, medium, High	Low, medium, High
Pause Time	0 to 9.9 seconds	0 to 9.9 seconds	0 to 5 seconds	0 to 5 seconds	0 to 5 seconds
Phases of Therapy Cycle	Insufflation, Exsufflation, Pause	Insufflation, Exsufflation, Pause	Insufflation, Exsufflation, Pause	Insufflation, Exsufflation, Pause	Insufflation, Exsufflation, Pause
Pegaso Cough Safety Protocols	Dynamic Flow and Pressure control. Manufacturer Software Calibration eliminates all undesired oscillations. Sensor malfunction detection	Dynamic Flow and Pressure control. Manufacturer Software Calibration eliminates all undesired oscillations.	Dynamic Stability Analysis. Flow and Pressure based Oscillation Detection Extreme Flow Rate Control and Response Sensor Malfunction Stability	N/A	Dynamic Stability Analysis. Flow and Pressure based Oscillation Detection Extreme Flow Rate Control and Response Sensor Malfunction Stability
Percussion Frequency	50 to 600 bpm	NA	60 to 1200 bpm	NA	NA
Remote Data Access	An internal memory stores therapies data. RS232/USB adapter transmits to a PC therapies and technical data.	NA		N/A	A secure digital (SD) card provides means for data access.

The table below provides a description of the modifications to the Dima Italia Srl *Pegaso Cough* device that are subject of this 510(k) submission:

Device Features	Similarities
User Interface	A new graphic display and a new graphical user interface with hierarchical menu system. **SIMILARITIES** **Philips Respironics CoughAssist T70** K121955 has similar parameters displayed in the main working page. **Philips Respironics CoughAssist T70** K121955 doesn't visualize oximetry parameters on the main page, but the operator has to call a specific function in order to visualize these monitored values. Pegaso (all models) visualizes on the main page the monitored values and the alarms and exceptions that are related to the oximetry.
EasyStart/AutoSync	A feature for patients who can provide a spontaneous breathing effort to trigger the Cough sequence, instead of using manual or auto modes therapy. This software feature monitors the device outlet flow and initiates the insufflation phase of therapy delivery when the flow increases over a set threshold indicative of patient effort. **SIMILARITIES** The AutoSync and Easy Start are based on the detection of the patient's inspiratory efforts (triggers). For this detection a digital flow sensor is used. The principle is similar to the **Philips Respironics CoughAssist T70** K121955 Cough-Trak feature.
Oscillations (Percussion)	A feature that delivers a pressure oscillation based on frequency and amplitude set points. **SIMILARITIES** The feature is similar to the oscillatory vibrations of the Philips Respironics SimplyClear (K122111). In the literature technicians prefer to use the Frequency and I/E Ratio instead of the definition of Inspiratory Time and Expiratory Time. The Pause Time is never used. So, Pegaso A-Cough Perc in the Percussion modality, shows Frequency and I/E Ratio.
Data Management	Therapy data will be stored in an internal memory. On request data are sent to a PC
Oximetry Connection	The devices has full compatibility with Masimo Set Technology Oximeters. The device displays current SpO2, Pulse rate, and Perfusion Index received from the oximeter. Minimum and maximum alarms values are present. The device complies with all clauses of ISO 9919:2009 **SIMILARITIES** The Pegaso devices (all models) work with a Masimo oximeter. The oximeter is similar to the one used on the **Philips Respironics CoughAssist T70** K121955 device.
Case	The case has been modified for higher ergonomics **using same materials**
Electrical Safety Class	The Electrical class is now Class II BF.
Labels	The NEW NEGAVENT DA-3 PLUS PEGASO name is substituted. The rear panel label reports now the commercial names *Pegaso Cough, Pegaso A-Cough, Pegaso A-Cough Perc* identifying the active options. A Barcode has been added, in which are repeated Date of production, device identification and serial number

Performance Data

Non-Clinical Testing.
In order to demonstrate that the *Pegaso Cough* device performs to design input specifications and it is substantially equivalent to predicate devices, black-box performance testing was conducted, using bench testing methodologies.
Worst case scenario inputs that would be experienced in the intended use environment has been simulated (null and maximum pressures, minimum and maximum flows, all SpO2 values and all Pulse rate values, all exceptions that external Masimo SpO2 module can activate).
Additional white-box testing verified proper operation under conditions of sensors malfunctions, inaccurate or complete sensor dropout.
For oximeter verification, a Clinical Dynamic Simulator Validation Report has been run by Masimo on *Pegaso Cough.*

Device Modification Testing Summary

Verification activities have been performed to verify that the device modifications stated above did not affect the safety and effectiveness of the subject device. This included bench testing, software unit testing, and code reviews.

Device Characteristics	**Testing Summary**
User Interface, including displayed therapy parameters and oximetry parameters.	Has been verified to meet product requirements defined for the Pegaso Cough. Bench testing, black-box and white-box testings, code reviews and software unit testing were performed to verify that all display functions, user controls and informational messages performed as intended, including oximeter values. The user interface was verified to ensure that it displayed the proper data and expected therapy information.
AutoSync/EasyStart	The AutoSync and EasyStart features of the Pegaso A-Cough and Pegaso A-Cough Perc device has been verified to meet product specifications with each defined patient case simulation. The operation and triggering performance has been verified to operate across tha range of patient cases.
Oscillations (percussion)	The Percussion feature of the Pegaso A-Cough Perc has been verified to meet product specifications. Bench testing at extreme therapy settings has been executed and waveforms on lung simulator are as attended.
Data Management	Data Management of the Pegaso Cough device has been verified to meet product specifications for internal EEprom and for its downloading from a PC. Bench testing, black-box and white-box testings, code reviews and software unit testing were performed to verify that all memory functions performed as intended.
Oximetry Connection	The oximeter has been tested to verify that the pulse oximetry data perform as intended. Proper values visualization and proper alarms activation has been tested, too. All exception messages have been verified with bench testing and with a clinical dynamic simulator.
Case	The Pegaso Cough structure and materials have been tested to verify the complying to product requirements defined for the device. IEC 60601-1, ISO 10993-1, ISO 9919 tests passed. **Third part Test reports.**
Electrical Safety Class	The Pegaso Cough has been tested to verify the complying to product requirements defined for the device. IEC 60601-1, IEC 60601-1-2 passed. **Third parts Test reports..**

Standards Evaluation

The Dima Italia Srl Pegaso Cough device has been 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 Electric 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. ISO 9919 Medical Electrical Equipment-Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
7. IEC 62304 Medical Device Software – Software life cycle precesses.

The Dima Italia Srl *Pegaso Cough, Pegaso A-Cough, Pegaso A-Cough Perc* were tested in accordance with applicable voluntary standards. The Dima Italia Srl *Pegaso Cough, Pegaso A-Cough, Pegaso A-Cough Perc* met the required performance criteria and functioned as intended.

Conclusion

Pegaso Cough, Pegaso A-Cough, Pegaso A-Cough Perc are equivalent devices.

The *Pegaso Cough, Pegaso A-Cough, Pegaso A-Cough Perc* modifications that are the subject of this 510(k) submission have been validated using non-clinical tests. A clinical dynamic simulator was used for the pulse oximetry validation.

The *Pegaso Cough, Pegaso A-Cough, Pegaso A-Cough Perc* devices have been determined to be substantially equivalent to the predicate devices. Bench testing (black-box and white-box) and software code reviews have confirmed that the *Pegaso Cough, Pegaso A-Cough, Pegaso A-Cough Perc* devices performs substantially equivalent to the cited predicated devices.

Pegaso Cough, Pegaso A-Cough, Pegaso A-Cough Perc devices are different from predicate devices on maximum percussion frequency (that is limited to 600cpm).

The indication for use, technological characteristics, and principles of operation are similar to the predicate devices. The Dima Italia Srl *Pegaso Cough, Pegaso A-Cough, Pegaso A-Cough Perc* devices are as safe and as effective to the predicate devices and the devices do not raise questions of safety and effectiveness