510(k) Summary

K072290

Owner: Dima Italia Srl
Via C. Vighi 29
Bologna, Italy 40133

Lewis Ward
Consultant

MAY 29 2008

Prepared 2-13-08

L.W. Ward and Associates, Inc.
4655 Kirkwood Court
Boulder, CO 80301
303-530-3279
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Device Trade Name: Pegaso V

Indications for Use:

The New Negavent Ventilator DA-3 Plus Pegaso V is a timed-cycled, pressure ventilator that is intended to support a patient's ventilation by alternately applying and releasing external negative pressure over the diaphragm and upper trunk of the patient. The ventilator works with a cuirass, poncho, or a ventilating chamber (Porta-Lung).

Classification Name: Positive Pressure Intermittent Breathing Device

Classification: 868.5935, Product Code BYT

Common Name: External Negative Pressure Ventilator

SE Predicate: Lifecare Services Inc.
NEV-100, Non-invasive Extrathoracic Ventilator
K910947
868.5935

Device Description:

The Pegaso V is an assisted/controlled non-invasive ventilation system. It can work with a cuirass, poncho, or a ventilating chamber (Porta-Lung). An optional Trigger can be installed, sensing the spontaneous demands of the patient and permitting the use in *Synchro/Timed*, *Spontaneous/Timed* and *Spontaneous with Plateau* modes. If the Triggers are installed, the *Autoparameters Function* is enabled too, permitting the evaluation of the Respiratory Frequency and I/E Ratio of the patient in automatic mode.

The Pegaso V is substantially equivalent to the Lifecare NEV-100. Equivalent technologies are used.

The negative pressure ventilation is a mechanical kind of ventilation similar to the human spontaneous ventilation. The Pegaso V is designed around 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 the atmosphere, compresses or depresses it in order to generate a pressure/depressure controlled by electronic sensors. Leaks are compensated cycle by cycle.

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 compressed flow go toward the patient and the depressed flow toward the atmosphere or, instead, the compressed flow to the atmosphere and the depressed flow toward the patient. The working parameters are displayed on an LCD and controlled through a touch keyboard.

The selectable parameters are:

- Respiratory Time
- Positive Pressure Value
- Negative Pressure Value

Device Safety is demonstrated through meeting device safety standards IEC, EN 60601-1-2, EN ISO 9703-3, EN 794-1, and EN 794-2.

Comparison Table

Feature	Lifecare NEV-100	Dima Italia Negavent DA-3 Plus Pegaso V
Indications for Use	An external negative pressure ventilator that is intended to support a patient's ventilation by alternately applying and releasing external pressure over the diaphragm and upper trunk of the patient. The ventilator works with a cuirass, poncho (body suit), or ventilating chamber (Porta-Lung).	A timed-cycled pressure ventilator that is intended to support a patient's ventilation by alternately applying and releasing external negative pressure over the diaphragm and upper trunk of the patient. The ventilator works with a cuirass, poncho (body suit), or ventilating chamber (Porta-Lung).
Line Voltage Frequency Power	 120-240Vac 50/60 Hz 500W/600W	 110-230Vac 50/60 Hz 400W
Use settings	Home, hospital, institution	Home, hospital, institution
Patient Use	Adult	Adult
Negative Pressure I	Adjustable -5 to -100 cm H_2O	Variable from 0 to -99 cm H_2O
Positive/Negative Pressure E	Unknown	Variable from +99 to -25 cm H_2O
Frequency	4 to 60 bpm	Variable from 5 to 50 bpm
I/E Ratio	Adjustable 1:0.5 to 1:29.1	Variable from 1/0.5 to 1/99 (based on present frequency and adjustable to clinician's selected setting)
Controls	Menu driven, software controlled	Menu driven, software controlled
Inspiratory Time (Ti)	0.5 to 5.0 seconds	0.1 to 5.0 seconds
Modes	- Controlled ventilation - Assisted controlled ventilation	- Controlled ventilation - Assisted controlled ventilation - Continuous negative - Assisted with Plateau
Alarms	- High and Low respiratory pressure - Power Failure - Constant Pressure - Internal failure	- High and Low respiratory pressure - Power Failure
Weight	31 pounds	14.3 pounds
Accessories	Patient Hose Optional proximal pressure line Nasal Cannula Operator's Manual	Power cord (230V,110V) Vacuum Airflow Tube Operator's Manual
Electrical Safety	UL, TUV, CSA	EN 60601

Feature	Emerson Cough Assist	Dima Italia Negavent DA-3 Plus Pegaso Cough
Standards	UL 747Y	EN 60601-1, EN 60601-1-2, EN 60601-1-4
EMC	UL, TUV, FCC Part 15, CSA, Class B	EN 60601-1-2, FCC Part 15, Class B
CE Conformity	Not listed	Risk Class IIb 93/42 EEC Directive CE 0476
Environmental Temperature	41° F to 104° F	50° F to 122° F

Pegaso V
Similarities and Differences

The Dima Italia ventilator is substantially equivalent to the Lifecare NEV-100 Non-invasive Extrathoracic Ventilator.

Similarities:

1. The products have equivalent Indications for Use.
2. The fundamental technology is the same. An electric powered blower produces positive and negative pressures. The pressures are alternately applied/released over the diaphragm and upper trunk of the patient.
3. Both devices meet safety evaluations under IEC 60601 standards.
4. Pressures developed are comparable.
5. Both units are available in 110V and 220/230V versions.
6. Both units are intended for adult patients.
7. Use settings for home, hospital, and institution are the same.
8. Frequencies of breaths are comparable.
9. Both systems are software controlled.

Differences:

No major differences.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 2008

Dima Italia SRL
C/O Mr. Lewis Ward
Consultant
L.W. Ward and Associates, Incorporated
4655 Kirkwood Court
Boulder, Colorado 80301

Re: K072290
Trade/Device Name: Pegaso V
Regulation Number: 21 CFR 868.5935
Regulation Name: External Negative Pressure Ventilator
Regulatory Class: II
Product Code: BYT
Dated: May 20, 2008
Received: May 23, 2008

Dear Mr. Ward:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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

510(k) Number (if known):

Device Name: Pegaso V

Indications for Use:

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Prescription Use __X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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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