K122560

MAR 26 2013

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Summary Date: July 30, 2012

2. Device Name: VersalVent Model V1 Hyperbaric Chamber Ventilator

Proprietary: VersalVent Model V1 Hyperbaric Chamber Ventilator

Common or Usual: Ventilator, Continuous, Facility Use

Classification: Continuous Ventilator (21 C.F.R. § 868.5895)

Product Code: CBK

3.Predicate Device: Providence Global Medical, Inc.'s Atlantis Hyperbaric Ventilator, K092264

4. Device Description: The VersalVent Model V1 Hyperbaric Chamber Ventilator provides ventilatory support for pediatric and adult patients who require mechanical ventilator support while undergoing hyperbaric chamber therapy under the direction of a physician. The Device is completely pneumatically operated by pressurized oxygen sources from the hospital main oxygen source or by oxygen cylinders. The Device provides controlled ventilation and imv ventilatory modes with operator-set inspiratory pressure relief capabilities as further described in Technical Characteristics on page S2.

The controls of the Device are easily found on the front panel and the integrated mechanical monitoring and safety systems provide for the breathing integrity of the patient at all times by the attending physician and healthcare professionals trained in hyperbaric oxygen/mechanical ventilator therapy.

5. Intended Use/Indications for Use: The VersalVent Model V1 Hyperbaric Chamber Ventilator is intended and indicated for use with pediatric and adult patients in respiratory failure or any other specific patient breathing requirements, as determined by the attending physician, when the patient is placed inside a hyperbaric chamber for prescribed therapy.

6.Technological Characteristics: The Device is comprised of two main modules: (1) the Control Module which is located outside the hyperbaric chamber; and (2) the Patient Breathing Circuit, which is located inside the hyperbaric chamber. These two modules are connected by four high-pressure hoses, which are passed through the chamber bulkhead by special connectors. The Control Module contains the functional controls that allow the operator to adjust inspiratory flow/volume, inspiratory time, imv oxygen flow and expiratory time. The Control Module also supplies oxygen through three of the high-pressure hoses to the brass manifold, then to the operator-selected, FDA-cleared, disposable patient tubing circuit and imv reservoir, which delivers oxygen to the patient. This patient tubing circuit is connected to the patient's Operator-supplied, FDA-cleared, disposable endotracheal tube.

As the chamber is pressurized or depressurized, the Patient Breathing Circuit supplies feedback pressure from inside the hyperbaric chamber through the fourth connecting hose, to the differential pressure regulator located within the Control Module. The regulator will increase or decrease output pressure to the flow/volume output control to compensate for chamber pressure changes, thereby keeping the delivered tidal volume constant. In the case of using the device inside a multiplace chamber, the differential pressure regulator will be controlled manually by its control knob located on the front panel.

The Substantial Equivalence Table, summarizing the similarities and differences between the device and its predicate, as well as a component listing with descriptions of operation, for both the device and predicate, are provided on Summary pages S3-S6.

VERSALVENT MODEL V1 HYPERBARIC CHAMBER VENTILATOR

	Pan-America Hyperbarics, Inc. VersalVent Model V1 Hyperbaric Chamber Ventilator (510(k) subject device)	**Providence Global Medical's Atlantis Hyperbaric Chamber Ventilator (K092264) (predicate device)**
Intended Use/Indications for Use	The VersalVent Model V1 Hyperbaric chamber Ventilator is indicated for use with pediatric and adult patients in respiratory failure or any other specific breathing requirements as determined by the attending physician, when the patient is placed inside a hyperbaric chamber for prescribed therapy.	The Atlantis Hyperbaric Chamber Ventilator is indicated for use with pediatric and adult patients in respiratory failure or any other specific breathing requirements as determined by the attending physician, when the patient is placed inside a hyperbaric chamber for prescribed therapy .
User Population	Adult and pediatric patients	Adult and pediatric patients
Technological Characteristics		
Power	Pneumatically powered	Pneumatically powered
Power Source	Pressurized Oxygen	Pressurized Oxygen
Device Components	Control Module, pressure adjusting output regulator, inspiratory flow/volume control, inspiratory time control, expiratory time control, bulkhead pass-through hoses, Patient Breathing Circuit, brass manifold, disposable patient tubing circuit with exhalation valve, airway pressure gauge, and pressure relief valve	Control Module, pressure adjusting output regulator, inspiratory flow/volume control, inspiratory time control, expiratory time control, bulkhead pass-through hoses, Patient Breathing Circuit, brass manifold, disposable patient tubing circuit with exhalation valve, airway pressure gauge, and pressure relief valve
Safety Features	Pressure relief valve, manual oxygen flush button, airway pressure gauge, exhalation valve opens with pneumatic pressure system failure	Pressure relief valve, manual oxygen flush button, airway pressure gauge, exhalation valve opens with pneumatic system failure
Labeling on machine	VersalVent name /all else similar	Atlantis name/all else similar

Direct Patient Contact	None; device is connected to patient via operator-supplied, FDA cleared, disposable, patient tubing circuit and endotracheal tube connector.	None; device is connected to patient via operator-supplied, FDA cleared, disposable, patient tubing circuit and endotracheal tube connector
Dimensions	L=12" x W=8" x H=9"	L=12" x W=8" x H=9"
Weight	12 lbs	12 lbs
Minute Volume Range	0-15 lpm at 6 ATA	0-15 lpm at 6 ATA
Tidal Volume Range	0-1.0 L at 6 ATA	0-1.0 L at 6 ATA
Breaths per Minute Range	8 to 40 bpm	8 to 40 bpm
Inspiratory Time Range	0.5 to 3.5 seconds	0.5 to 3.5 seconds
Expiratory Time Range	0.5 to 5.0 seconds	0.5 to 5.0 seconds
I:E Ratio Range	1:5 to 3.5:1	1:5 to 3.5:1
Inspiratory Flow Range	0 to 100 lpm at 1 to 6 ATA	0 to 100 lpm at 1 to 6 ATA
Humidification	Operator provided, if needed	Operator provided, if needed.
Airway Pressure Gauge	-10 to +100 cm H_2O manometer	-10 to +150 cm H_2O manometer
Power Consumption	1.0 lpm, oxygen	1.0 lpm, oxygen
Inspiratory Pressure Limit	0 to 85 cm H_2O adjustable pressure relief valve	0-100 cm H_2O adjustable pressure relief valve

Mechanical Components and Descriptions, for both the Device and Predicate

a. Differential-pressure Regulator - This device is powered by the incoming oxygen source that also supplies all pneumatic components in the Control Module. The Differential-Pressure Regulator receives a gas pressure signal from the hyperbaric chamber via one of the four hoses attached to the Control Module and then to the hyperbaric chamber, which allows the regulator to increase or decrease its output pressure to compensate for pressure changes in the chamber. This allows the inspiratory flow/volume output to stay constant. A panel-mounted, manual control knob may also be used for fine tuning of pressure output as the operator desires.

(continued, following)

b. Inspiratory Flow/Tidal Volume Valve - This valve receives its oxygen input from the Device's source gas , allowing the operator to adjust the needle valve control knob to regulate the prescribed output for each breath.

c. Inspiratory Timing Valve - This valve controls the time that the inspiratory flow valve receives gas flow from the Device's source gas, and is adjusted by the operator via a control knob. When the inspiratory time has elapsed, the expiratory time valve begins its timing.

d. Expiratory Timing Valve - This valve controls the time that the expiratory phase keeps the inspiratory gas flow at zero. The operator adjusts this valve via a control knob. When the expiratory time has elapsed, the inspiratory time begins the inspiratory-expiratory cycle over again.

e. Intermittent Mandatory Ventilation (IMV) Flow Valve-this valve controls the imv oxygen flow from the control module to the imv reservoir located inside the chamber. The operator adjusts the oxygen flow to the reservoir bag by direct observation and by the inspiratory needs of the patient.

f. Timing Valves Control Pressure Gauge - This gauge indicates the preset control pressure regulator that powers the timing valves system. This regulator is preset at the factory, allowing the operator to understand the displayed value, in case it varies from the factory-preset pressure.

g. Chamber Pressure Gauge - This gauge allows the operator to observe the pressure inside the chamber during compression and decompression phases in order to compare such pressures to other pressure gauges located on the control deck of the hyperbaric chamber itself, and allow for proper manipulation of the manual controls knobs simultaneously.

h. Differential Pressure Regulator, Pressure Gauge - This gauge allows the operator to observe the indicated output of the differential pressure regulator pressure and compare it to source gas input pressure and chamber pressure, during pressurization and depressurization.

i. Source Gas Adjustable Pressure Regulator Gauge-This operator-supplied output pressure adjustable regulator with attached pressure gauge, mounted onto a large oxygen supply cylinder, allows the operator to observe the preset procedure gas pressure from the oxygen cylinder which supplies oxygen pressure to the entire Control Module of the Device. The oxygen source is primarily an "H" size oxygen cylinder, or a manifolded, multiple, "H" size oxygen cylinder system provided by the operator.

(continued following)

j. Patient Breathing Circuit System – The Patient Breathing Circuit system is connected to the Control Module by three of the four high-pressure hoses that are connected from the Control Module to the hyperbaric chamber. (the 4th hose provides a pathway for a gas signal back to the Control Module-see "a" above).

The incoming flow/volume hose is attached to the brass manifold, to which are mounted, the disposable patient tubing circuit, imv reservoir bag, airway pressure gauge, pressure relief valve and inspiratory gas line. The exhalation valve driveline is connected to the exhalation valve diaphragm inlet port, located on top of the exhalation valve body. The third incoming hose bypasses the brass manifold and attaches directly to the imv reservoir bag inlet connector.

B. Safety Features

a. Pressure Relief Valve - This valve is adjusted before the ventilation procedure begins, to an operator- prescribed inspiratory pressure limit to be allowed during the hyperbaric therapy session. This valve prevents over-pressurization of the patient's lungs during the inspiratory phase of each breathing cycle. This valve is attached to the brass manifold. The predicate device prv adjustable upper limit is 15 cmH2O higher than the Device's prv; predicate higher limit is not used clinically.

b. Exhalation Valve - This valve, an integral part of the patient tubing circuit, closes during the inspiratory phase thereby allowing inspired oxygen to go to the patient, then opens during the exhalation phase of the cycle and permits exhaled gases to vent to ambient. In addition, the patient may inhale through the opened exhalation valve in the event that the mechanical inspiratory phase does not occur.

c. Airway Pressure Gauge - This gauge allows the operator to observe the patients airway pressure during the procedure.

d. Oxygen Flush Button - This manual control, located on the front panel of the Control Module, allows the operator to deliver an inspiratory phase breath at any time in the unlikely event of control module failure.

There are no other mechanical components for either the Device or Predicate.

(Section 6.b.1, Summary, for K122560)

Nonclinical Data: The VersalVent Model V1 Hyperbaric Chamber Ventilator has undergone extensive individual, or side-by side bench and actual hyperbaric chamber testing (comparing the device to the predicate) for verification, validation and design safety testing which all confirms that the Device meets its design , performance and safety requirements, and is substantially equivalent to the Predicate.

Please see **Sections 17 (2011), 18 and 19 (2012)** for complete Testing information.

Please see **Response to Requested Information Noted in FDA Reviewer's Letter , Dated Friday, October 19, 2012, Sent to FDA Reviewer February 15, 2013.**

6.b.2

Conclusions: The Device and the Predicate have the same intended use and same indications for use, the same technological characteristics, the same mechanical components and the same principles of operation. The only design differences between the Device and its Predicate are the labels indicating the difference in trade names, the slight difference in pressure relief valve maximum relief pressures (Device =85 cmH20 vs Predicate= 100 cmH2O) and the patient airway pressure gauge maximal pressure indications (Device =100 cmH20 vs Predicate=150 cmH2O) which do not pose significant differences in operational output or patient safety between the Device and Predicate.

Testing, using the Device only (Section 17) and the Device and Predicate (Section 18 and 19) show conclusively that the Device and Predicate operate in the same fashion and that all output parameters are the same **regarding pressure, volume and flow waveforms as indicated on the clear plastic testing sheets found in Section 18, Performance Testing and in the Response to FDA-Requested Information dated February 15, 2013.**

In the "Response" reply to the FDA- questions, we also provided verification and validation testing information regarding oxygen gas inlet and device oxygen output testing and separately for representative tidal volume delivery.

In that same document we also provided typical and worse case conditions for use with the modes of ventilation delivery and clinical justification for such mode(s) of ventilation across the board for the intended patient population.

In addition, in that same document we provided laboratory analysis and conclusions for EPA TO-15/1 and PM 2.5.

Therefore, the VersalVent Model V1 Hyperbaric Chamber Ventilator is Substantially Equivalent to the Predicate and has superseded the testing provided by the Predicate.

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

March 26, 2013

Pan-America Hyperbarics, Incorporated
C/O Mr. William M. Gates, RRT
1510 Park Place Drive
ATCHISON KS 66002

Re: K122560
Trade/Device Name: VersalVent Model V1 Hyperbaric Chamber Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: February 15, 2013
Received: February 22, 2013

Dear Mr. Gates:

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 for
-S FDA

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

K122560

5. Indications for Use Statement

Device Name: VersalVent Model V1 Hyperbaric Chamber Ventilator

Indications for Use: r

The VersalVent Model V1 Hyperbaric Chamber Ventilator is indicated for use with pediatric and adult patients in respiratory failure or any other specific breathing requirements, as determined by the attending physician, when the patient is placed inside a hyperbaric chamber for prescribed therapy.

Prescription Use___ And/Or Over-the counter Use___

(Part 1 C.F.R. 801 Subpart D) (21 C.F.R. 801 Subpart C)

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

Concurrence of DCRH, Office of Development (ODE)

Albert E. Moyal -S (for LS)

c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000933 1, cn=Albert E. Moyal -S 2013.03.21 17:10:53 -04'00'

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

510(k) Number: K122560