NOV 3 1998

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K982454

RESPIRONICS INC.
1001 Murry Ridge Lane, Murrysville, PA 15668

Official Contact	David J. Vanella Manager, Regulatory Affairs Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 Telephone: (724) 733-0200
Classification Name	21 CFR 868.5895,73 MNT
Common/Usual Name	Ventilator, Continuous
Proprietary Name	BiPAP Vision® Ventilatory Support System
Predicate Devices	**Respironics BiPAP S/T-D 30** – K955324 Respironics, Inc.

BiPAP and BiPAP Vision are registered trademarks of Respironics, Inc.

Substantial Equivalence to Predicate Devices

The SE Comparative Analysis performed in the Section 510(k) Premarket Notification for the BiPAP Vision demonstrates that it compares favorably with the two predicate devices in the provision of engineered safety features and alarm functions, and that it is substantially equivalent to them, both in its intended use, and in its safety and effectiveness for the comparable operating modes, viz., CPAP and Spontaneous with Timed breaths as a backup (S/T). The SE Analysis, thus, allows the conclusion that the BiPAP Vision presents no additional concerns regarding safety or effectiveness.

Furthermore, testing was performed to demonstrate that the performance of the BiPAP Vision in its intended environment is as safe and effective as that of each of the legally marketed predicate devices. The BiPAP Vision has been found to be in compliance with, and has been certified to, the standards referenced in the "Draft FDA Reviewer Guidance for Premarket Notifications, November 1993." The effectiveness of the BiPAP Vision has been further established through testing to the performance requirements of ASTM F 1100-90 and the "Draft Reviewers Guidance For Ventilators", July 1995.

Intended Use

The BiPAP Vision Ventilatory Support System is an assist ventilator and is intended to augment patient breathing. It is not intended to provide the total ventilatory requirements of the patient. The BiPAP Vision Ventilatory Support System is intended for spontaneously breathing adult patients suffering from acute respiratory failure, acute or chronic respiratory insufficiency, or obstructive sleep apnea in hospitals, or other institutional settings, under the direction of a physician. It may also be indicated for intubated patients meeting the same selection criteria as the noninvasive applications. Operators of the BiPAP Vision are expected to be physicians, nurses and respiratory therapists. The patient would not be responsible for ventilator control. The BiPAP Vision is used with various combinations of Respironics-approved patient circuit accessories, such as patient interface devices (masks and headgear assemblies, endotracheal tube elbow adapter), humidifiers, and circuit tubing.

Device Description

Introduction

The BiPAP Vision can provide therapy in the modes of continuous positive airway pressure (CPAP), and pressure support ventilation, with preset, machine assisted breaths available as a backup to the patient's respiratory spontaneity, i.e., the Spontaneous/Timed (S/T) mode. Both modes of operation of the BiPAP Vision provide accurate and reliable delivery of pressurized air, at flows sufficient to accommodate the needs of adult patients (≥ 30 kg). The BiPAP Vision is a microcontroller-based, pressure assist, critical care, continuous ventilator that has been provided with digital and analog process control and variable monitoring capabilities, and a comprehensive array of alarms, engineered safety features and self diagnostic functions. The BiPAP Vision architecture, and the electrical, mechanical and material specifications of all system components were selected to optimize performance and reliability. The BiPAP Vision also incorporates a number of safety features and self-diagnostic testing capabilities.

A Liquid Crystal Display (LCD) video screen mounted on the front of the unit, together with an array of keys and a rotary adjustment knob, provide the primary user interface with the BiPAP Vision. The display includes waveform or bargraph representation of the process variables, and a digital display of the control settings and any alarm conditions. User interaction with the device is accomplished by keystrokes and rotation of the adjustment knob while observing the results of this manipulation on the display. The information provided on the display varies depending on the operating mode and/or the operations being performed. The Vision is shown in Figure 12.1

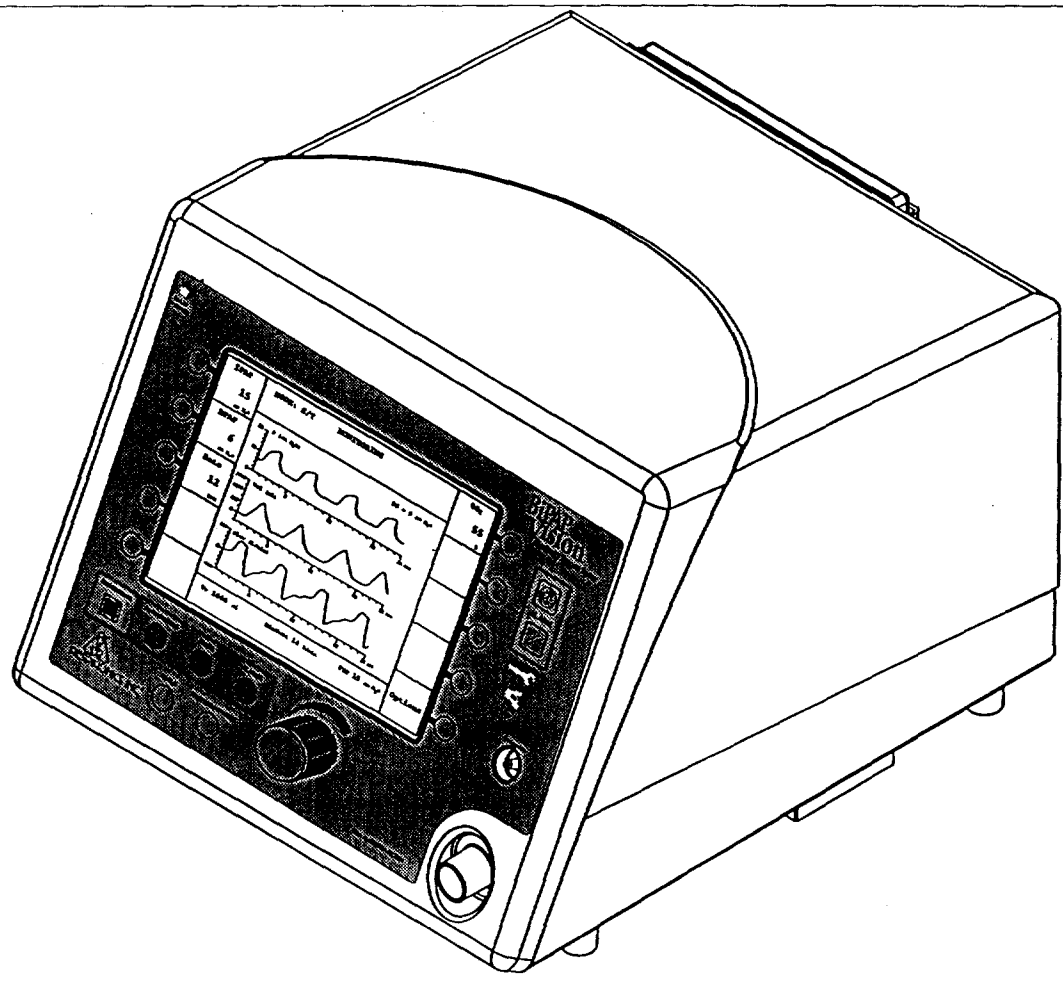


Figure 12.1 -- The BiPAP Vision Ventilator

Principles of Operation

Ambient air is drawn in through an integral air intake filter, and pressurized in a centrifugal blower assembly. System total flow and pressure are regulated by means of a valve assembly located in the blower discharge manifold.

As mentioned previously, a Liquid Crystal Display (LCD) video screen mounted on the front panel of the unit is the primary user interface with the BiPAP Vision. It provides a continuous display of total gas flow, temperature, generated pressure, and patient circuit pressure to ensure prescribed therapy to the patient.

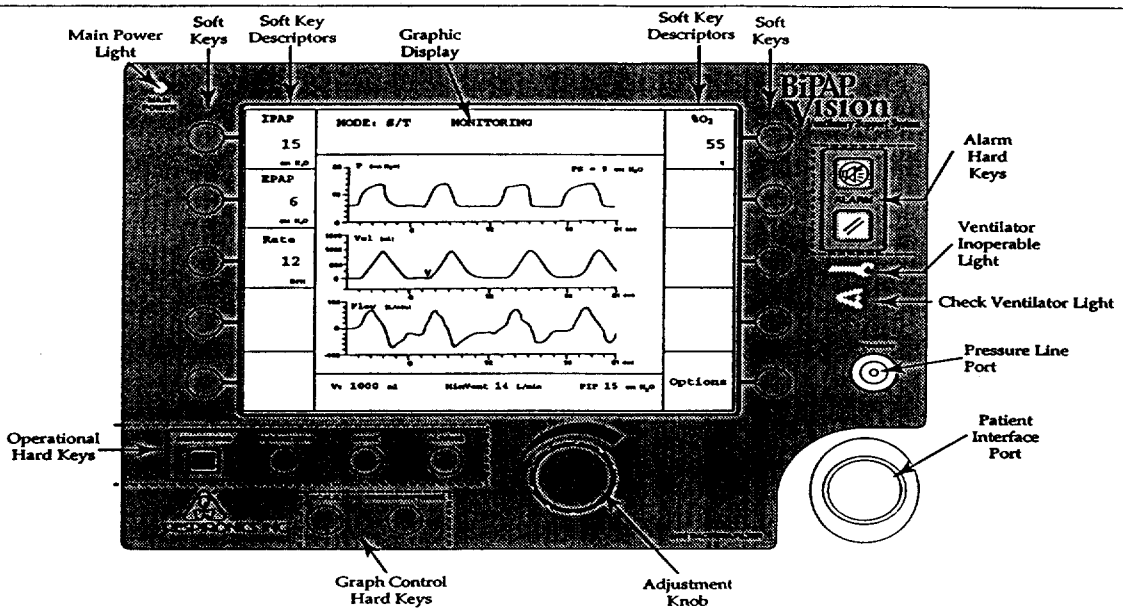


Figure 12.2 -- BiPAP Vision Front Panel: Controls and Displays

The front panel, shown in Figure 12.2, has a rotary adjustment knob, eight hard-keys, and ten soft-keys to establish the ventilatory parameters, alarm settings and the ventilator graphics. The hard-keys are mechanical key switches dedicated to specific functions regardless of the mode of operation. They become active or inactive based on the screen currently displayed in the Graphic Display Area. The hard key functions are: Monitoring, Mode, Parameters, Alarms, Scale, Freeze/Unfreeze, Alarm Silence, and Alarm Reset. The soft-keys are dome-key switches, the functions of which change depending upon the displayed screen or the current mode. The soft-key function is displayed in the soft-key descriptor area that is immediately adjacent to the key. The Rotary Adjustment Knob allows the user to adjust the values of the ventilatory parameter that has been "activated" with a soft-keystroke. The knob is "active" only when a soft-key is used to select a parameter.

Triggering and Cycling Logic

In the S/T operating mode the BiPAP Vision employs enhanced triggering/cycling logic that accommodates variable leak conditions and patient breathing patterns, thereby minimizing early triggering and delays in cycling, and resulting in improved patient-ventilator synchrony. The BiPAP Vision senses when to trigger and cycle in accordance with established rule sets.

System Configurations

The Phoenix BiPAP Vision Basic Unit is equipped with the standard alarm package (i.e., High Pressure, Low Pressure and Delay, and Apnea).

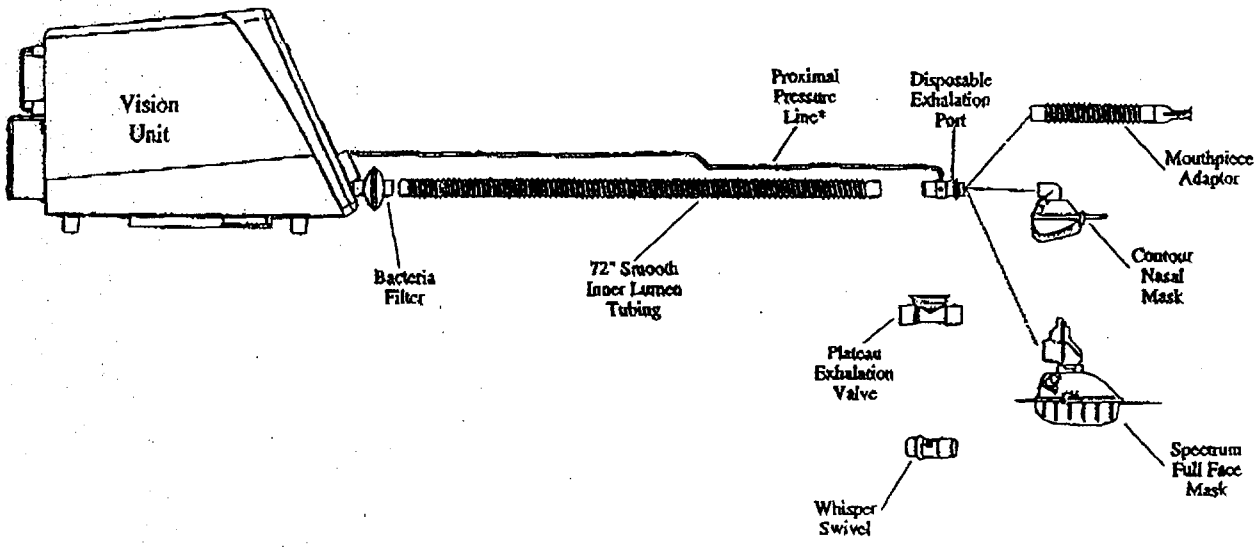
Options

(Available as product "upgrades")

- Oxygen Module
- Mobile Stand

Patient Circuit Configurations

The BiPAP Vision Ventilator is intended for use with a patient circuit specifically approved by Respironics, Inc. All the patient circuits that Respironics has approved for use with the BiPAP Vision are illustrated in Figure 1.4(a) - (c).



*The proximal pressure line may connect to either the exhalation port or to the mask (when a mask is used).

Figure 1.4(a) – Typical Approved BiPAP Vision Patient Circuit For Noninvasive Patient Interfaces

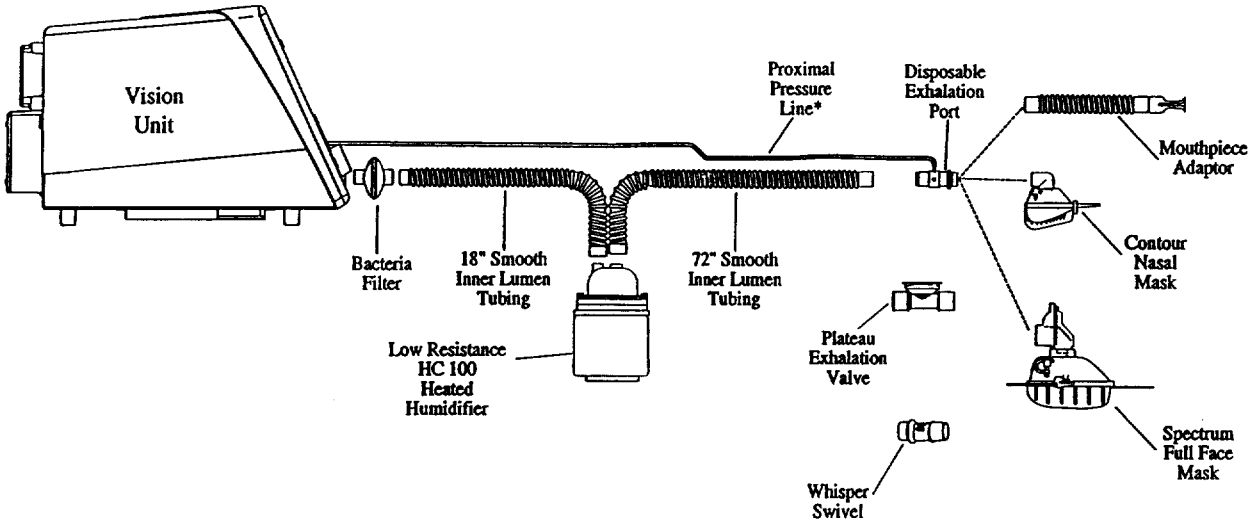


Figure 1.4(b) -- Approved BiPAP Vision Patient Circuit With Optional Humidifier

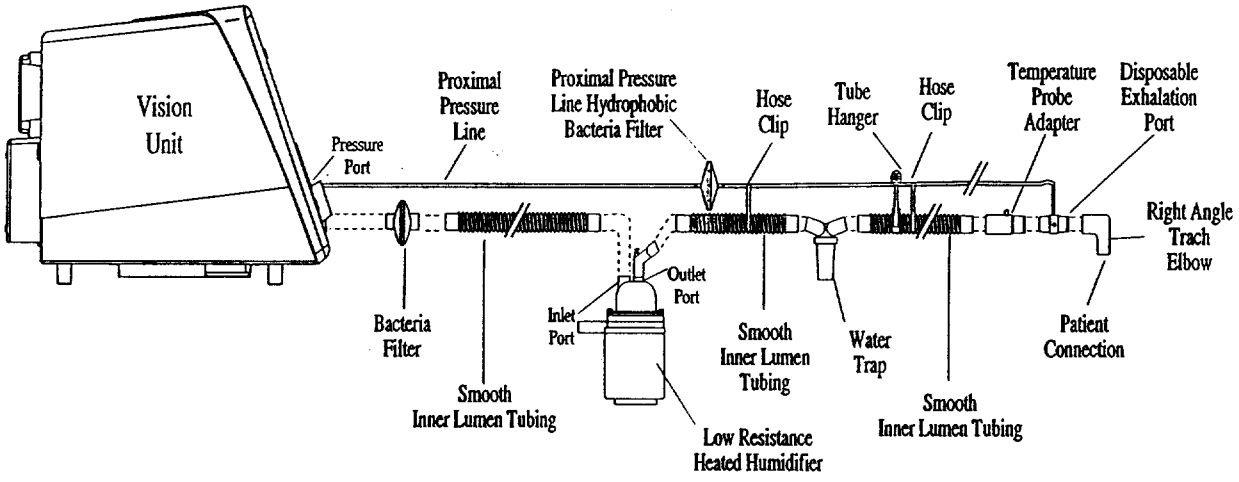


Figure 1.4(c) -- Approved BiPAP Vision Patient Circuit For Invasive Applications

As depicted in Figure 1.4, the Respironics-approved patient circuit consists of the following components:

- a bacteria filter;
- a transparent proximal pressure line (1/8" I.D.) with a smooth inner lumen;
- a patient circuit tube with smooth inner lumen;

- an exhalation device such as the Whisper Swivel, Respironics Disposable Exhalation Port assembly, or Plateau Exhalation Valve; and
- a Respironics noninvasive or invasive patient interface.

Also, as an option,

- a Heated humidifier

Patient Circuit Components and Accessories

- Disposable Noninvasive Circuit:

  Includes 72 inch tubing, exhalation port, 84 inch proximal pressure line, hanger, and hose clips.

- Disposable Invasive Circuit:

  Includes circuit tubing, exhalation port, water trap, humidifier, proximal pressure line, hanger, hose clips, and airway adapter.

- Circuit Tubing:

  72 inch disposable circuit tubing
  18 inch disposable circuit tubing
  36 inch disposable humidifier tubing
  Disposable proximal pressure line with tee

- O_2 enrichment attachment
- Disposable bacteria filter
- Water Trap, Model No. 073-0072-95, manufactured by Marquest, Inc
- Exhalation Ports:

  Disposable exhalation port
  Whisper Swivel® exhalation port
  Plateau™ exhalation port

- Patient Interfaces

  Masks:

  Disposable vinyl masks
  Reusable contour nasal masks
  Spectrum™ disposable full face mask
  Comfort Flap® mask accessory
  Disposable mouthpiece adapter

Mask Accessories:

Disposable headgear
Reusable headgear
Chin strap
Softcap™
Slip-on spacers

Endotracheal Tube Interface:

Marquest Tracheal Tube Elbow Adapter

- Humidifiers:

Fisher & Paykel MR730 Respiratory Humidifier
disposable chambers recommended for invasive applications

- Hardware:

Circuit Support Arm
Mobile Stand
Humidifier Pole Mount

Summary of the Functional and Performance Testing Conducted

As mentioned previously, in addition to the SE Comparative Analyses, the determination of substantial equivalence of the Vision with its predicate devices is based on performance testing that was conducted to demonstrate it to be safe and effective in its intended environment. Thus, the safety of the BiPAP Vision Ventilatory Support System, i.e., the BiPAP Vision with the Respironics-approved circuits and accessories, was verified through performance testing that consisted of Electrical Safety, Electromagnetic Compatibility, and Mechanical and Environmental testing. Again, the BiPAP Vision was found compliant and has been certified to the applicable sections of the following standards, as referenced in the "Draft FDA Reviewer Guidance for Premarket Notifications, November 1993":

- IEC 601-1: General Requirements for Safety of Medical Electrical Equipment;
- IEC 801-1: Electromagnetic Compatibility for Industrial Process and Measurement and Control Equipment, Part 1;
- IEC 801-2: Electrostatic Discharge Requirements;
- IEC 801-3: Radiated Electromagnetic Field Requirements;
- IEC 801-4: Electrical Fast Transients/Burst Requirements;
- CISPR 11: Limits and Methods of Measurement of Radio Interference Characteristics of Industrial, Scientific, and Medical Equipment;
- IEC 68-2-6: Basic Environment Test Procedures, Part 2: Tests. Test Fc and Guidance: Vibration (Sinusoidal);
- IEC 68-2-27: Basic Environment Test Procedures, Part 2: Tests. Test Ea and Guidance: Shock;
- IEC 68-2-34: Basic Environment Test Procedures, Part 2: Tests. Test Fdc: Random Vibration Wide Band - Reproducibility Low;
- MIL-STD-461D: Requirements for Control of Electromagnetic Interference Emissions and Susceptibility;
- MIL-STD-462D: Measurements of Electromagnetic Interference Characteristics; and
- MIL-STD-810E: Environmental Test Methods

Thus, the safety and effectiveness of the BiPAP Vision was verified by a comparative analysis of the predicate devices; functional testing of the device against product specifications; and, testing to ASTM F 1100-90, and the performance requirements of the FDA Reviewers Guidance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 1998

Mr. David J. Vanella
Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668-8550

Re: K982454
BiPAP Vision Ventilatory Support System
Regulatory Class: II (two)
Product Code: 73 MNT
Dated: October 14, 1998
Received: October 15, 1998

Dear Mr. Vanella:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K982454

Device Name: BiPAP Vision ® Ventilatory Support System

Indications for Use:

Intended Use/Indications for Use

The Respironics BiPAP Vision® Ventilatory Support System is an assist ventilator intended to augment the breathing of spontaneously breathing adult patients (>30 kgs) suffering from respiratory failure, respiratory insufficiency, or obstructive sleep apnea. It is not intended to provide the total ventilatory requirements of the patient. It is intended to be used for both invasive and non-invasive applications.

The BiPAP Vision is intended for use in a hospital environment (including sleep labs, respiratory care units) or alternate care site (e.g., transitional care centers, skilled nursing homes, ambulatory care centers) by respiratory therapists, sleep lab technicians or nurses under the supervision or direction of a physician.

The BiPAP Vision is used with various combinations of Respironics-approved patient circuit accessories, such as patient interface devices (masks and tracheal tube adapter), humidifiers, and circuit tubing.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K982454

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)