SECTION 1

SUMMARY OF SAFETY & EFFECTIVENESS

RESPIRONICS INC.®
1001 Murry Ridge Drive, Murrysville, PA 15668

Official Contact	David J. Vanella Manager, Regulatory Affairs Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
Classification Reference	21 CFR 868.5895
Common/Usual Name	MNS (continuous ventilator, non-life-supporting)
Proprietary Name	BiPAP® Synchrony™ HC
Internal Project Name	Vireo
Predicate Device	Respironics Quantum™ PSV (K962517)
Reason for submission	New Device

Substantial Equivalence

This premarket notification section 510(k) submission demonstrates that the BiPAP® Synchrony™ HC is substantially equivalent to, and has the same intended use as, the Respironics Quantum PSV.

Testing was performed to demonstrate that the performance of the BiPAP® Synchrony™ HC in its intended environment is as safe and effective as that of the legally marketed predicate device. The safety and effectiveness of BiPAP® Synchrony™ HC were verified through performance-related testing in addition to electrical safety, electromagnetic compatibility, mechanical and environmental testing. The BiPAP® Synchrony™ HC was tested and found compliant (as applicable for Code MNS)

with the standards referenced in the "Draft FDA Reviewer Guidance for Ventilators," July 1995 as well as with the "Draft Reviewer Guidance for Premarket Notifications, "November 1993.

Intended Use/Indications for Use

The BiPAP® Synchrony™ HC is a non-invasive, pressure support ventilator used to

i) Augment the breathing of patients suffering from acute or chronic respiratory insufficiency

ii) Maintain airway patency and provide ventilatory support to patients who experience obstructive sleep apnea.

It is not intended to provide the total ventilatory requirements of the patient.

The BiPAP® Synchrony™ HC is intended for use with nasal masks and full-face masks as recommended by Respironics.

Environment of Use/Patient Population

The BiPAP® Synchrony™ HC is intended for use in the home, but may also be used in the hospital or other institutional settings.

The BiPAP® Synchrony™ HC is intended for adult patients (>30kg).

Brief Device Description

The BiPAP® Synchrony™ HC is a noninvasive pressure support ventilator and is classified under product code MNS (continuous ventilator, non-life supporting).

The BiPAP Synchrony HC provides therapy in the Continuous Positive Airway Pressure (CPAP) Spontaneous/Timed (S/T), Pressure Assist, and Timed modes.

CPAP Mode

In this mode, a clinician can set CPAP.

- The device delivers CPAP to the patient at the CPAP setting.

Spontaneous/Timed (S/T) Mode

The clinician sets IPAP, EPAP, Rate, and Inspiratory Time.

- The device delivers patient-triggered, pressure-limited, patient-cycled breaths if the patient's breathing rate is above the Rate setting.
- The device delivers machine-triggered, pressure-limited, time-cycled breaths if the patient's breathing rate falls below the Rate setting. The Inspiratory Time setting controls the triggering of the inspiratory phase. The Inspiratory Time setting does not affect the cycling of a spontaneous breath.

Pressure Assist Mode

The clinician sets IPAP, EPAP, Rate, and Inspiratory Time.

- The device delivers machine or patient-triggered, pressure-limited, machine-cycled breaths.
- This mode is equivalent to the S/T mode with one exception: all breaths are machine-cycled and therefore have a fixed Inspiratory Time. The patient may initiate a breath but all breaths will be pressure-limited (IPAP) and time-cycled. The cycle time is determined by the Inspiratory Time control setting.
- The patient-controllable Rise Time may enhance patient–ventilator synchrony and patient comfort.

Timed Mode

The clinician sets IPAP, EPAP, Rate, and Inspiratory Time.

- The device delivers machine-triggered, machine-cycled breaths. The triggering is determined by the Rate control, and the cycle time is determined by the Inspiratory Time control.

Features

PERFORMANCE

- Provides non-invasive application of CPAP and bi-level pressure support ventilation.
- Provides spontaneous triggering based on the Respironics Auto-Trak™ Sensitivity system.
- Compensates for most leaks in the patient circuit and patient interface.
- Compensates the unit outlet pressure for flow based pressure drops in the patient circuit.

SAFETY

- Provides built-in alarms for high pressure and low pressure.
- Provides internal circuit monitoring for safety.
- Provides an optional oxygen valve that closes when the blower is off, preventing oxygen flow.
- Provides a patient disconnect alarm with a time delay that is set by the clinician.

Figure 1 shows the BiPAP® Synchrony™ HC system, which includes:

- BiPAP® Synchrony™ HC unit
- Circuit tubing
- Patient interface
- Exhalation port

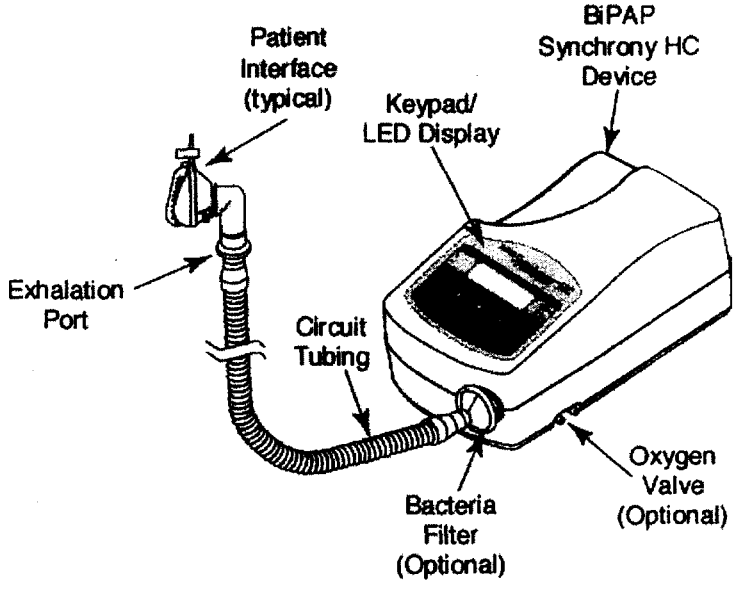


Figure 1. BiPAP® Synchrony™ HC System.

BiPAP® Synchrony™ HC Accessories

The BiPAP® Synchrony™ HC can be used with various combinations of Respironics-approved patient circuit accessories, such as patient interface devices (masks and headgear assemblies), humidifier, and circuit tubing.

(End of Section.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 20 2000

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

Re: K992530
BiPAP® Synchrony™ HC
Regulatory Class: II (two)
Product Code: 73 MNS
Dated: December 30, 1999
Received: January 3, 2000

Dear Mr. Vanella:

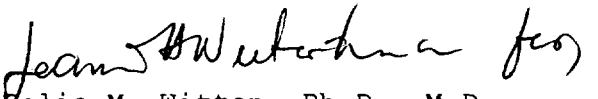
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992530

Device Name: Respironics® BiPAP Synchrony™ HC

Intended Use/Indications for Use

The BiPAP Synchrony is intended to provide non-invasive ventilation in adult patients (>30kg) for the treatment of respiratory insufficiency (a condition in which the patient can continue without ventilation for some period, such as overnight) or obstructive sleep apnea. The Synchrony ventilator is intended for use with nasal masks and full-face masks as recommended by Respironics.

Environment of Use/Patient Population

For use in the home or hospital/institutional environment on adult patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

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