

MAY 19 1998

K984407

Premarket Notification Section 510(k)  
Section 1 - Summary of Safety and Effectiveness

BiPAP Harmony S/T

## SECTION 1

### EXECUTIVE SUMMARY / SUMMARY OF SAFETY & EFFECTIVENESS



**RESPIRONICS INC.**<sup>®</sup>

1001 Murry Ridge Drive, Murrysville, PA 15668

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<b>Official Contact</b>	David J. Vanella Manager, Regulatory Affairs Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
<b>Classification Reference</b>	21 CFR 868.5895
<b>Common/Usual Name</b>	continuous ventilator, non-life-supporting
<b>Proprietary Name</b>	BiPAP Harmony S/T
<b>Internal Project Name</b>	Harmony LS
<b>Predicate Device</b>	Respironics Quantum PSV (K#962517)
<b>Reason for submission</b>	New Device

### Substantial Equivalence

This premarket notification section 510(k) submission demonstrates that the BiPAP Harmony S/T 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 Harmony S/T in its intended environment is as safe and effective as that of the legally marketed predicate device. The safety and effectiveness of BiPAP Harmony S/T were verified through performance-related testing in addition to electrical safety, electromagnetic compatibility, mechanical and environmental testing. The BiPAP Harmony S/T 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 Harmony S/T is a non-invasive, pressure support ventilator used to augment the breathing of patients suffering from acute or chronic respiratory insufficiency, or to 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.

## **Environment of Use/Patient Population**

The BiPAP Harmony S/T is intended predominantly for use in the home, but may also be used in the hospital or other institutional settings.

The BiPAP Harmony S/T is intended for adult patients (>30kg).

## **Brief Device Description**

The BiPAP Harmony S/T is a noninvasive pressure support ventilator and is classified under product code MNS (ventilator, continuous, non-life supporting). It is an electromechanical device and contains no software.

The BiPAP Harmony S/T ventilator provides therapy in a Spontaneous/Timed (S/T) mode. A 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 duration of the inspiratory phase. The inspiratory time setting does not affect the cycling of a spontaneous breath.

## Features

### PERFORMANCE

- Provides non-invasive application of bi-level and continuous positive airway 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, low pressure, and pressure regulation.
- Provides internal circuit monitoring for safety.
- Provides an optional oxygen valve that closes, preventing oxygen flow, when the unit is turned off or power fails.
- Provides a patient disconnect alarm with a time delay that is set by trained personnel.

Figure 1 shows the BiPAP Harmony S/T system, which includes:

- BiPAP Harmony S/T unit
- Circuit tubing
- Patient interface
- Exhalation port

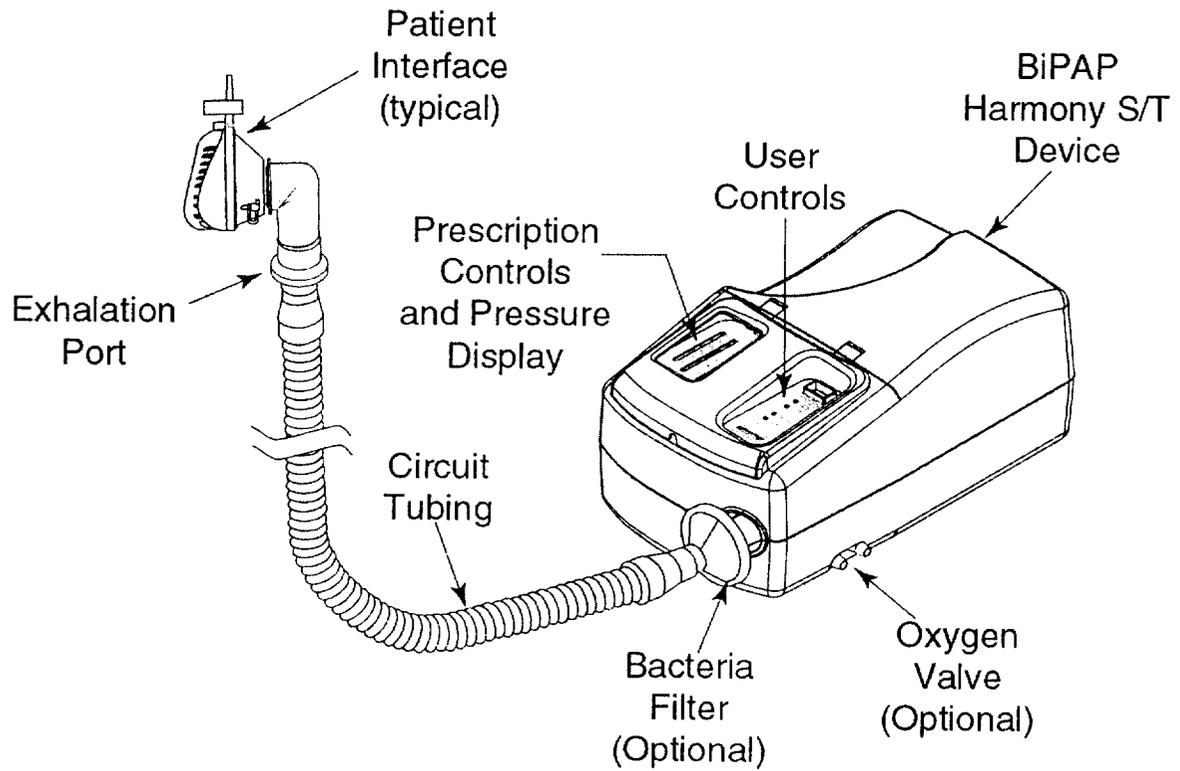


Figure 1. BiPAP Harmony S/T System.

## BiPAP Harmony S/T Accessories

The BiPAP Harmony S/T can be used with various combinations of Respiration-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

MAY 19 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. David J. Vanella  
Manager, Regulatory Affairs  
RESPIRONICS®, Inc.  
1001 Murry Ridge Dr.  
Murrysville, PA 15668

Re: K984407  
Trade Name: BiPAP Harmony S/T, Model 1001445  
Regulatory Class: II  
Product Code: MNS  
Dated: February 23, 1999  
Received: February 25, 1999

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.

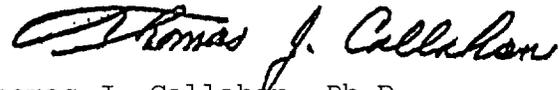
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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) 594-4586. 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" (21CFR 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): K984407

Device Name: BiPAP Harmony S/T

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use  
(Optional Format 1-2-96)

  
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(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K984407