ATTACHMENT 4

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Official Contact	David J. Vanella Manager, Regulatory Affairs Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
Classification Reference	21 CFR 868.5905
Product Code	BZD – noncontinuous ventilator
Common/Usual Name	CPAP System
Proprietary Name	Respironics® Virtuoso LX Smart CPAP System
Predicate Device	Virtuoso Smart CPAP System (K953930)
Reason for submission	Modified design; additional accessories

Substantial Equivalence

The modified device has the following similarities to the previously cleared predicate device:

- ❑ Same intended use.
- ❑ Same operating principle.
- ❑ Same technology.
- ❑ Same manufacturing process.

Design verification tests were performed on the Virtuoso LX Smart CPAP System as a result of the risk analysis assessment, and acceptance criteria were met. Respironics has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the device described in this submission is substantially equivalent to the predicate device.

The modified device complies with the applicable standards referenced in the "Draft FDA Reviewer Guidance for Premarket Notifications," November 1993.

Intended Use/Device Description

The Virtuoso LX Smart CPAP System is intended for the treatment of adult Obstructive Sleep Apnea. The Virtuoso LX Smart CPAP System is a blower-based system that generates positive airway pressures from 3 to 20 cm H_2O. The device is intended for use with a patient circuit that connects to the CPAP device to route the air to patient via a nasal mask. The patient circuit consists of six-foot 20 mm tubing, an exhalation device and a nasal mask. These basic characteristics of the Virtuoso LX Smart CPAP device have not changed as compared to the predicate device, the Virtuoso Smart CPAP System K953930.

The Virtuoso LX Smart CPAP System is a microprocessor-controlled device that produces Continuous Positive Airway Pressure known as CPAP. One of the primary components in the CPAP device is the blower that generates airflow. The blower assembly consists of an impeller coupled to a brushless DC motor assembled in a plastic housing. When energized, the blower draws ambient air through an air filter, pressurizes it, and provides the Therapeutic Pressure to the patient via the patient circuit.

Device Modifications

The modifications to the Virtuoso Smart CPAP device consist of the following:

1. The addition of a removable data card. The removable data card is a credit card-size data recorder that is installed into the side of the Virtuoso LX Smart CPAP device. The data card has two functions:

- **Data Retrieval:** The data card records device usage data from the Virtuoso LX Smart CPAP device for evaluation by the Home Care Provider and/or physician to better monitor patients who suffer from Obstructive Sleep Apnea. The data card can be mailed from the patient to the Home Care Provider to download device usage data onto a personal computer. The data that is retrievable from the data card consists of device information i.e., blower on/off time, CPAP pressure, ramp time, ramp start, ramp completion time, and answers to the Functional Outcome of Sleep Questionnaire (FOSQ). Currently, the Home Care Provider must first obtain the patient's device and download the information directly via RS 232. The information, accompanied with patient survey data, is collected for evaluation.
- **Device Settings:** The removable data card can also be used to transfer new or updated prescriptions to the patients device. Periodically, prescriptions change for various reasons. The typical procedure is for the Home Care Provider to manually change the device to reflect the new prescription. The data card is merely a convenience feature that eliminates the need for the Home Care Provider to be present to change the prescription pressure setting on the Virtuoso LX Smart CPAP device.

Device Modifications

When the patient inserts an updated data card with a new prescription into the machine, the prescription is entered into memory and is automatically deleted from the data card.

2. The addition of the Encore Data Management Software: The Data Management Software resides on a personal computer. The Encore Data Management Software uploads usage data from the data card. The Encore Data Management Software presents graphical and statistical analysis on the device usage. It enables the Home Care Provider to access patient compliance and maintain patients' therapeutic history. It also enables the physician to download updated prescriptions onto the data card which is then sent to the patient via the Home Care Provider. The software does not perform any scoring or diagnosing. The Encore Data Management software views information from Obstructive Sleep Apnea patients who previously have been diagnosed. We have included in Attachment 1 the User Interface Screens for the Encore Data Management Software.

3. The addition of the "Functional Outcomes of Sleep Questionnaire" (FOSQ)[1]. When prompted by the Home Care Provider, the patient can access the Virtuoso Smart CPAP System menu to answer specific questions regarding their quality of life. The written questions are located inside the User Manual for the patient to read. The answers to the questionnaire are entered via the Virtuoso Smart device keypad and stored on the data card for later download. The purpose of the questionnaire is to determine if CPAP therapy has improved a patient's quality of life. Currently, the Home Care Provider sends the patient the questionnaire to manually complete and return..

4. Energy type: The Virtuoso LX Smart CPAP now includes a switching power supply. The device accepts the same input voltages but does not require a manual voltage selector switch. This modification has no impact on the safety or effectiveness of the device.

5. Revised Time Meter: The time meter now reads actual therapy time by detecting patient breathing by monitoring a combination of parameters such as pressure and motor speed. Previously, the device measured Blower On time. The design is substantially equivalent to the time meter design incorporated in the Respironics (Healthdyne) Model 1700 Tranquility Bilevel System K970173 cleared in April, 1997.

[1] Weaver T, Laizner A, Evans L, Maislin G, Chugh D, Lyon K, Smith P, Schwartz A, Redline S, Pack A, Dinges D. An instrument to measure functional status outcomes for disorders of excessive sleepiness. *Sleep* 1997; Suppl. 20(10):835-843.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 1999

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

Re: K993433
Virtuoso® Smart CPAP System
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: October 8, 1999
Received: October 12, 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) 594-4648. 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,

Wolf Sapirstein, 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): K993433

Device Name: Respironics® Virtuoso Smart LX CPAP System

Intended Use/Indications for Use

The Virtuoso Smart LX CPAP System delivers continuous positive airway pressure therapy for the treatment of Obstructive Sleep Apnea.

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, Neurological Devices
510(k) Number