SECTION 12

SUMMARY OF SAFETY & EFFECTIVENESS

K961626

RESPIRONICS INC

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Classification Name	21 CFR 868.5905, 73 BZD
Common/Usual Name	Ventilator, Noncontinuous
Proprietary Name	Solo CPAP System
Predicate Devices	Aria CPAP System - K953341 Respironics, Inc. 1001 Murry Ridge Drive Murrysville, PA 15668 Companion 314 Nasal CPAP System - K952292 Nellcor Puritan-Bennett 10800 Pflumm Road Lenexa, KS 66215

Reason for Submission

The Solo CPAP System is a new device.

Substantial Equivalence

This premarket notification section 510(k) submission demonstrates that the Solo CPAP System is substantially equivalent to the Respironics Aria CPAP System (K953341) and the Nellcor Puritan-Bennett Companion 314 Nasal CPAP System (K952292), both of which are used to treat adult Obstructive Sleep Apnea.

Testing was performed to demonstrate that the performance of the Solo CPAP System in its intended environment is as safe and effective as that of the legally marketed predicate devices. The safety and effectiveness of the Solo CPAP System were verified through performance-related testing that consisted of Electrical Safety, Electromagnetic Compatibility, Mechanical and Environmental Testing. The Solo CPAP System was tested and found compliant with the standards referenced in the "Draft FDA Reviewer Guidance for Premarket Notifications," November 1993.

General Technical Description

Intended Use

The Respironics Solo CPAP System is intended to deliver Continuous Positive Airway Pressure (CPAP) therapy for the treatment of adult Obstructive Sleep Apnea (OSA) only. The Solo CPAP System may be used in clinical settings (hospitals & sleep labs) and in home environments, and must be prescribed by a physician. It is not intended for life support or life sustaining applications. The device is used in conjunction with a mask (various styles and sizes available), headgear, and a combination of breathing circuit accessories.

Contraindications

Studies have shown that the following pre-existing conditions may contraindicate the use of CPAP therapy for some patients:

- Bullous Lung Disease
- Pathologically Low Blood Pressure
- Severe Cardiac Arrhythmias
- Coronary Artery Disease
- Pneumothorax
- Pneumomediastinum
- Pneumocephalus has been reported in a patient using nasal Continuous Positive Airway Pressure. Caution should be used when prescribing CPAP for susceptible patients such as those with: cerebral spinal fluid (CSF) leaks, abnormalities of the cribriform plate, prior history of head trauma, and/or pneumocephalus.

The use of positive airway pressure therapy may be temporarily contraindicated if you exhibit signs of a sinus or middle ear infection. Contact your physician if you have any questions concerning your therapy.

Note: "Seizures" have been inaccurately listed as contraindicated for Respironics CPAP therapy products (refer to the Aria CPAP System labeling, for example). There is no clinical basis for this claim. Consequently, Respironics has corrected the Solo CPAP System contraindications by deleting "seizures" from the list. This is in keeping with the labeling of other CPAP devices.

Summary of the Device Description

The Solo CPAP System is an electromechanical device that produces Continuous Positive Airway Pressure (CPAP) and delivers it to a patient. As shown in Figure 12-1, the system consists of the Solo CPAP device and a patient circuit that is used to direct the air to the patient.

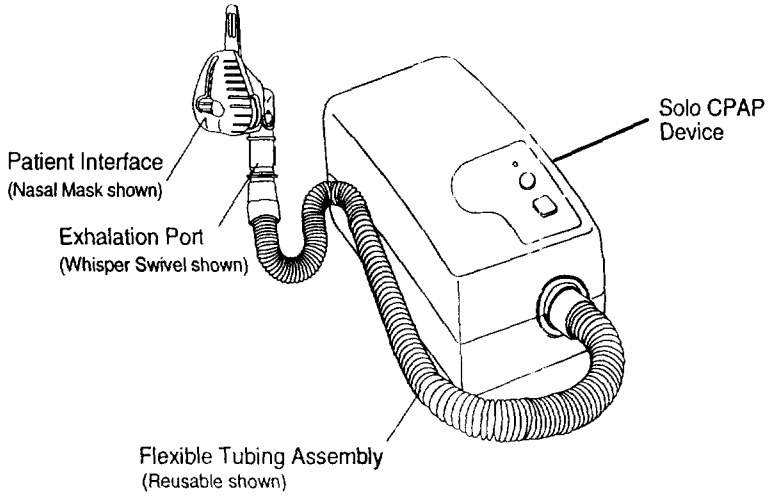

Figure 12-1. Solo CPAP System

The Solo CPAP device consists of a blower assembly and a microprocessor control system. The blower assembly generates positive airway pressures from 4 to 15 cm H_2O. The level of pressure is dependent on motor speed. Two control buttons (Pressure ON/OFF and Ramp) and an LED are located on the control panel at the top of the unit. Motor speed is controlled by a microprocessor-controlled feedback system. (The control panel and software control system are each detailed separately later in this section.) The device can operate on either 115 or 230 Volts AC, or 12 volts DC using the DC accessories included with the system. The Solo CPAP device incorporates DC operation to provide portability for patient use of the device when away from home where AC voltage is not accessible. The Solo CPAP System offers DC power as an alternative power source; it is not intended to be used as a battery back-up source. The Solo CPAP System is not intended to be used in a mobile environment.

Pressurized air travels from the Solo CPAP device to the patient via 22 mm flexible tubing. The flexible tubing connects with an exhalation port to exhaust

carbon dioxide from the circuit, which in turn connects to a mask. The tubing, exhalation port, and mask are referred to as the patient circuit.

Principles of Operation

Control Panel

The control panel located on top of the Solo CPAP device shown in Figure 12-2 consists of two control buttons (Pressure ON/OFF and Ramp) and an LED. The control panel is the user interface, which allows the therapist or patient to operate, monitor, and control the Solo CPAP System. The Pressure ON/OFF button activates the blower to start delivering pressure and the Ramp button activates the Ramp feature (explained below). The LED provides operational status and will indicate when the Solo CPAP System is energized and/or if a system fault is recognized.

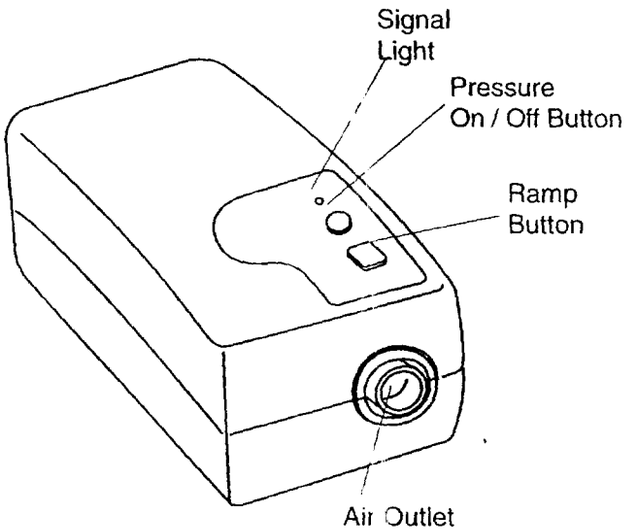

Figure 12-2. The Solo CPAP System Control Panel

Alternate Function of Controls

In addition to their specifically labeled functions, the Pressure ON/OFF and Ramp buttons allow for adjustment of Therapeutic Pressure and Elevation Compensation. The Therapeutic Pressure can only be set by the therapist or home care dealer and the design incorporates a lockout mechanism (detailed in Solo CPAP Software Control System) to prevent patient tampering. The

Elevation Compensation is a feature of the device that allows the patient to adjust the blower speed to compensate for elevation changes.

When Ramp is activated, it first decreases the pressure to a lower level (4 cm) so that patients can fall asleep more comfortably. It then incrementally increases the pressure over a specified time (Ramp time is approximately 20 minutes) until the Therapeutic Pressure is reached.

Solo CPAP Software Control System

The Solo CPAP System has an embedded software control system. Its software has been designed and developed in accordance with the FDA Reviewer's Guidance for Computer Controlled Medical Devices.

The software consists of several assembly language routines that provide the necessary functions for operation of the Solo CPAP System. A brief discussion of the software is described below.

- The software controls and regulates the patient pressure, via an algorithm that monitors and controls motor speed.
- The software monitors the specifically labeled functions of the Pressure ON/OFF and Ramp buttons, as well as their alternate functions (Therapeutic Pressure adjustment and Elevation Compensation).
- Built-in self tests verify various hardware and software conditions. These checks include monitoring a watch-dog timer, locked rotor checking, checksum memory errors, motor speed, and power loss.
- The Patient Mode allows the patient to change specified parameters. These parameters are Pressure ON/OFF, Ramp and Elevation Compensation.
- The Therapy Mode allows the home care dealer, therapist, or sleep lab technician to change specified parameters. The Therapy Mode is initiated by holding down the user Pressure ON/OFF and Ramp buttons while simultaneously plugging in the unit. This combination of actions constitutes the Therapy Mode's lockout feature. The only operating parameter that can be adjusted in this mode is the Therapeutic Pressure setting.

Solo CPAP System Accessories

The accessories intended for use with the Aria CPAP System are also intended for use with the Solo CPAP System. The accessories have not been modified since the Aria was determined substantially equivalent. Please refer to K953341 for complete accessory information.

Two additional accessories intended for use with the Solo CPAP System are the Respironics GEL™ Mask (K954207) and Monarch™ Mini-Mask (K945938). Please refer to those cleared 510(k)s for complete information.

The following table lists the accessories that are available for use with the Solo CPAP System, the manufacturer, and the reference number under which each accessory received 510(k) clearance.

Table 12-1. Solo CPAP System Accessories

Accessory	Reference 510(k)
Respironics Contour Nasal Mask and headgear	K851396
Respironics Spectrum™ Disposable Full Face Mask and headgear	K936047
Respironics Comfort Flap® Mask Accessory	K953341 (Aria CPAP System)
Respironics 6' Reusable Flexible Tubing Assembly Respironics 6' Disposable Flexible Tubing Assembly Respironics 18" Reusable Flexible Tubing Assembly Respironics 18" Disposable Flexible Tubing Assembly	K900113 (REMstar Choice® Nasal CPAP System)
Respironics Whisper Swivel® Exhalation Port	K883825 (BiPAP® System)
Respironics Plateau™ Exhalation Valve	K925587
Respironics Passover Humidifier	K945782
Fisher & Paykel Heated Humidifier	K915460C
King ViroBac Bacteria Filter	K880681
Respironics GEL™ Mask and headgear	K954207
Respironics Monarch™ Mini Mask and headgear	K945938
DC Accessories: DC Power Cord Battery Adapter Cable	K953341 (Aria CPAP System)