K030985

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

OCT 15 2003

Submitter:

Vital Signs, Inc.
20 Campus Road
Totowa, NJ 07512-1200

Contact Person:

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Summary Date:

July 16, 2003

Name of Device:

Breas PV10i CPAP System

Common Names:

CPAP System

Self-adjusting CPAP System

Auto-adjusting CPAP System

Classification Name:

Non-continuous ventilator (21 CFR 868.5905)

Product Code:

73 BZD

Predicate Devices:

Breas PV100 CPAP System (K001553)

ResMed Sullivan Autoset® T
(K970516, K970771, and K984428)

Device Description:

In the treatment of sleep disorders, CPAP is well established and common practice as a means to prevent upper airways from collapsing and therefore avoid breathing problems associated with airway collapse and obstruction. There are a number of devices legally marketed in the United States for this application, including self-adjusting CPAP systems such as the predicate ResMed Sullivan Autoset®T. The self-adjusting systems accommodate pressure requirements that may vary (e.g., as patients change bodies positions or enter different sleep stages).

The Breas PV10i CPAP is similar to the predicate Breas PV100 CPAP System, but with the addition of self-adjusting pressure features. Both Breas devices are microprocessor controlled based on firmware (embedded software). Both designs incorporate pressure sensors that monitor output pressure and provide feedback to the microprocessors. The PV10i also incorporates an airflow sensor and flow signal processing means in firmware to provide self-adjusting capability.

The therapy delivered by the Breas PV10i CPAP System can be either:

1) Self-adjusting in response to variations in patient breathing patterns (CPAP "i" mode), or

2) Set to a constant pressure level (constant CPAP mode).

The primary hardware component is a blower that generates airflow. The blower assembly consists of a brushless DC motor that drives a fan, entraining ambient air through a filter and pressurizing it to provide the prescribed airflow with CPAP for the patient. The microprocessor controls the motor and hence the speed of the fan.

The PV10i pressure range is 4 – 20 cmH_20. Starting pressure and self-adjusting pressure limits are settable by clinical personnel in accordance with the patient's prescription.

The CPAP airflow is delivered via a single lumen outlet tube that may be connected to various non-invasive patient interfaces, such as nasal masks. To minimize CO_2 rebreathing, masks or other interfaces permitting a leak flow of at least 12 liters/minute at the minimum output pressure setting of 4 cm of H_20 are recommended for use with the PV10i.

The pressure transducer incorporated in the PV10i continuously monitors output pressure to the patient and reference ambient pressure. This enables the device to automatically compensate for altitude changes.

The PV10i has an auto-switching power supply that facilitates use in conjunction with international travel (100 – 240 VAC). It can also be used with an external 12 – 24 VDC power source when AC mains line voltage is not available. This DC power source

capability is not intended as a battery power back-up system for any critical treatment applications. An accessory Remote Control Module may be connected that enables clinicians to operate the PV10i without using the control and setting panels on the device itself. A PC-based software program may also be supplied that provides an optional means for clinicians to set patient parameters (e.g., start and limit pressures) and track patient compliance.

The PV10i and its accessories are not sterile. The outer dimensions of the PV10i housing are 6.3 × 4.5 × 9.3 inches, and the device weighs 3.7 pounds.

Intended Use:

The Breas PV10i CPAP System is intended to deliver Continuous Positive Airway Pressure (CPAP) therapy for the treatment of adult Obstructive Sleep Apnea (OSA).

Comparison of Use and Technological Characteristics:

The PV10i may be used in clinical settings (e.g., hospitals, sleep laboratories, sub-acute care institutions) and home environments and must be prescribed by a physician. It is not intended for life support or life sustaining applications or for transport of critical care patients.

As compared with the cited predicate devices, the Breas PV10i CPAP System has:

Same intended uses

Same environments of use

Similar design (microprocessor-controlled blower as air source)

Same technology (software based flow signal processing means to provide self-adjusting pressure capability)

Same materials (with particular reference to the air flow pathway)

The differences that do exist are minimal and involve primarily user preference features. These features are described in labeling for the device that includes an Operator Manual.

Summary of Performance Testing:

1. Non-clinical testing was conducted to verify that the Breas PV10i CPAP System is capable of meeting its stated performance specifications and that all Risk Analysis issues have been appropriately addressed. The device passed all tests.

2. Testing was conducted to demonstrate compliance with applicable requirements in the November 1993 draft "Reviewer Guidance for Premarket Notification Submissions" published by the FDA's Division of Cardiovascular, Respiratory, and Neurological Devices. The testing included but was not limited to:

    - Electrical Safety testing per IEC 601
    - Electromagnetic Compatibility testing (EMC testing)
    - Mechanical Safety testing
    - Environmental testing
    - Functional testing

    The PV10i device passed all tests.

3. All device software (the embedded software and the optional PC software) was documented and tested in accordance with the FDA's May 29, 1998 "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices". The PV10i software passed all tests.

4. Two clinical studies were performed as part of the process of validating the software algorithm for the PV10i CPAP System's self-adjusting pressure features. They involved direct comparisons with predicate devices.

    A) In a three-way randomized crossover study involving 12 patients (of whom 11 completed all treatments) with symptomatic obstructive sleep apnea, the PV10i in self-adjusting mode was compared with the predicate ResMed AutoSet®T (K980721) and with conventional constant CPAP. Efficacy evaluation was based on analysis of sleep disordered breathing and sleep parameters assessed by nocturnal polysomnography. Further study outcomes were quality of life assessment and subjective preference of each device with respect to comfort.

    No significant differences were noted in sleep or ventilatory variables between the devices (mean apnea-hypopnea index (AHI) 6.8, 4.0 and 1.8 with PV10i, Autoset T and constant CPAP respectively). The PV10i applied lower mean pressure (6.7) as compared with the Autoset T (8.4) ($p<0.05$), and both self-titrating devices applied significantly lower mean pressure as compared with constant CPAP (9.4) ($p<0.01$). One patient could not be treated effectively with either self-adjusting pressure device due to increased arousability from sleep. This patient was effectively treated with manually titrated CPAP. Patients preferred self-adjusting CPAP pressure over constant pressure CPAP treatment (10 vs. 1, $p<0.01$).

    B) In a randomized treatment study evaluation involving initially 100 patients with apnea-hypopnea syndrome, four self-adjusting CPAP devices from

different manufacturers and conventional constant CPAP were compared. The study included comparison of results for a titration night and for a period of home use, with follow-up after three and six months. The self-adjusting CPAP devices included in this study were the Breas PV10i, the ResMed AutoSet®T (K980721), the Mallinckrodt GoodKnight® 418P (K993584), and the Weinmann SomnoSmart®.

Conclusions were based on apnea-hypopnea indices (AHI), Epworth sleepiness scores, and patient compliance. The PV10i patient group had a mean AHI of 55.6 initially, of 6.3 after titration and of 7.5 after 6 months. The comparable values were 56.5, 5.5 and 3.6 respectively for the predicate AutoSet T device and 48.5, 4.3 and 3.4 for the predicate Goodnight 418P. All four of the self-adjusting CPAP devices included in the study were judged to be efficient (efficacious) for home treatment.

Conclusions:

The Breas PV 10i CPAP System meets its stated performance specifications and criteria outlined in the Reviewer Guidance publications referenced above. Non-clinical test results and clinical studies demonstrate performance substantially equivalent to predicate devices. We conclude that the device is capable of operating safely in its intended environments and will be effective in fulfilling its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2003

Mr. Anthony P. Martino
Vice President of Quality Assurance & Regulatory Affairs
Vital Signs, Incorporated
20 Campus Road
Totowa, New Jersey 07512-1200

Re: K030985
Trade/Device Name: Breas PV10i CPAP System
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: July 23, 2003
Received: July 24, 2003

Dear Mr. Martino:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

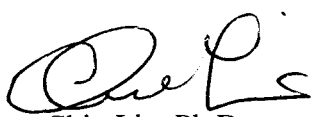
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
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Enclosure

510(k) Number: K030985

Device Name: Breas PV 10i CPAP System

Indications for Use: The Breas PV 10i CPAP System is intended to deliver Continuous Positive Airway Pressure (CPAP) therapy for the treatment of adult Obstructive Sleep Apnea (OSA).

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030985

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)