K092362

510(k) Summary

510(k) Owner: Circadiance LLC.
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Murrysville, PA 15668
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NOV - 2 2009

Establishment Registration Number: 3006182632

Contact Person: David G. Groll, CEO

Date Prepared:

Trade Name: SleepWeaver™ Nasal CPAP Mask

Common Name: Nasal Mask

Classification Name: Non-continuous Ventilator IPPB

Regulation Number: 21 CFR 868.5905

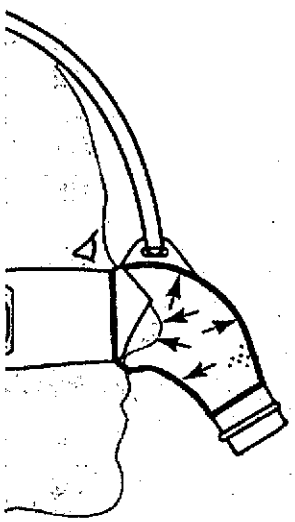
Product Code: BZD

Regulatory Classification: Class II

Legally Marketed

Predicate Devices:
Respironics ComfortLite™ Nasal Mask K082558- BZD
Resmed Mirage Swift Nasal Mask K042403- BZD

Device Description:



The SleepWeaver™ Nasal CPAP Mask serve as a mechanism for reliably connecting an adult patient diagnosed with sleep apnea to a source of continuous or bilevel positive air pressure needed to maintain an open airway. The nasal masks are fastened over a patient's nose by use of an `elastic strap around the head. A cloth cushion contacts the patient's face. The mask assembly has a tubing connection which is compatible with the industry standard 22mm air tubing.

Air is supplied to the mask by a CPAP device (the CPAP device can be a standard CPAP or Bi-Level type device). The patient inhales air from the mask and exhales into the mask where continuous airflow from the CPAP device purges the exhaled carbon dioxide from the mask through the mask exhaust vents.

Statement of Intended Use:

The SleepWeaver Nasal CPAP Mask is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or bi-level therapy. This mask is intended for single-patient reuse in the home and multi-patient, multi-use in the hospital/institutional environment. This mask is to be used on patients greater than 66 lbs/ 30 kg.

Technological Characteristics Comparison:

The SleepWeaver Nasal CPAP Mask is strapped to the patient's face covering the nose, and connected via 22mm tubing to a source of continuous or Bilevel positive air pressure, creating an airway splint in the throat. Positive pressure ventilation is thus applied to the lungs in a non-invasive way. The mask is made entirely of cloth which provides a comfortable, secure and leak-free interface with the patient. The positive pressure within the system keeps the cloth mask open during use, while providing a leak-free interface to the patient's face. The SleepWeaver Nasal CPAP Mask is equivalent in functional characteristics to the existing legally marketed predicate devices. The devices all function in providing a reliable mechanism of connection to a continuous or Bilevel positive air pressure source for the treatment of Obstructive Sleep Apnea.

The only new technology that has been introduced in the SleepWeaver Nasal CPAP Mask device is the use of cloth for the interface. This cloth cushion improves patient comfort over the use of a plastic cushion. Not only does the cloth make the mask more comfortable, the SleepWeaver™ Nasal CPAP Mask is the softest, smallest, most lightweight and flexible mask available. The single biggest determinant in achieving patient compliance with CPAP therapy is patient comfort. The single biggest reason for non-compliance is discomfort from or dissatisfaction with the CPAP Mask. So the SleepWeaver Nasal CPAP Mask offers a new choice to CPAP patient's to provide a more comfortable alternative to the hard plastic masks currently available on the market (see Appendix A, section 2)

The fundamental property of the mask that increases user comfort is that it operates like a balloon. The mask has no structure, and without air pressure it is floppy, like the throat of a person having an apnea. But once the CPAP pressure is applied, the mask inflates like a balloon. The air pressure inside the mask pushes the cloth surface against the patient's face. The mask takes on the contour of the patient's facial structure. Since the mask acts like a balloon, and all points in a balloon have the same pressure, the mask makes a leak-free seal with no pressure points.

The SleepWeaver Soft Cloth CPAP Mask is made entirely of cloth. The cloth is 100% polyester that is used to produce clothing, so there are no concerns about allergic or contact reactions, which is an issue for plastic masks. Cytotoxicity and skin irritation data (Appendix B) demonstrate no reactivity of the cloth material. Certain versions of cloth containing polyurethane have also been tested with no reactivity, but these alternative materials are not currently used in the product.

The mask can be used on Adult (30 Kg and up) Obstructive Sleep Apnea patients using CPAP or Bi-level systems. It has been tested at pressures from 4 – 20 cm H2O.

The mask features a series of pin holes that serve as an exhalation vent. The air coming out of these holes is very diffuse and quiet. There is no whistling or whooshing sound from the exhalation vent and no jet of air blowing on the bed partner. If the user holds their hand six inches away from the exhalation vent they can barely feel the air flow from the mask. Yet the exhalation vent provides comparable leak performance to the ResMed Mirage Swift Nasal Pillow System and the Respironics ComfortLite Nasal mask (Appendix A, section 1).

The SleepWeaver mask does not touch the bridge of the nose and can be worn while wearing glasses, which benefits people like to read in bed or watch TV before they go to sleep.

The SleepWeaver is a Nasal mask, which fits over the nose, so there is nothing that goes inside of the nostrils to irritate the inside of the nose. The SleepWeaver will work for patients who have previously used hard plastic nasal masks, hard plastic nasal prongs or a hard plastic full masks mask, but who are not mouth breathers. Mouth breathers can use the SleepWeaver Nasal CPAP Mask in conjunction with a chin strap.

The SleepWeaver Nasal CPAP Mask allows the patient to sleep on either side or their back. They can switch sides during the night. The patient can even lay on their face and the mask will stay sealed, unlike conventional hard plastic CPAP masks, which are easily dislodged by the pillow. One of the problems with all hard plastic CPAP masks and nasal pillows is that when the patient rolls over and the mask contacts the pillow, the force on the side of the mask causes it to lose its seal. The SleepWeaver Nasal CPAP Mask overcomes this problem. If a person contacts the mask to the pillow, the mask just conforms to the pillow without losing its seal.

The mask can be cleaned by hand washing in a mild detergent or in a washing machine on a gentle cycle. The mask will last over six months with normal care. In the Sleep Lab, the mask can be disinfected between patients with a high level disinfectant like Control III.

Cloth may be considered to be less durable that molded plastic. The feature most likely to be affected by the cloth wearing out is the leak rate through the exhalation ports and other inadvertent leaks in the mask. If the mask is wearing out, the leak rate will increase. So the testing conducted to qualify the SleepWeaver™ Nasal CPAP Mask emphasizes verifying the leak rate (both fixed and inadvertent) of the mask is acceptably low when the mask is initially removed from the package, after it has been stored for a long time, and after it has been cleaned multiple times. The cleaning is considered to be the process which is most likely to cause deterioration of the material in the mask. The testing included (Appendix A, sections 5 & 6) with this submission demonstrates that the material used to produce the SleepWeaver™ Nasal CPAP Mask is very durable. Not only is the leak rate matched to the predicate devices, even after 6 months of use (as simulated by 180 washings), the leak rate through the mask is effectively the same as a new mask.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV - 2 2009

Mr. David G. Groll
Chief Executive Officer
Circadiance, L.L.C.
3554 North Hills Road
Murrysville, Pennsylvania 15668

Re: K092362
Trade/Device Name: SleepWeaver™ Nasal CPAP Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Non-Continuous Ventilator IPPB
Regulatory Class: II
Product Code: BZD
Dated: July 27, 2009
Received: August 4, 2009

Dear Mr. Groll:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: SleepWeaver™ Nasal CPAP Mask.

Indications for Use:

The SleepWeaver™ Nasal CPAP Mask is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or bi-level therapy. This mask is intended for single-patient reuse in the home and multi-patient, multi-use in the hospital/institutional environment. This mask is to be used on patients greater than 66 lbs/ 30 kg.

Prescription Use _X_ OR Over-The Counter Use _____

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schulte

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

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