K120757

APR 2 4 2012

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Date of Submission	March 13, 2012
Classification Reference	21 CFR 868.5905
Product Code	BZD – ventilator, non-continuous (respirator)
Common/Usual Name	Nasal CPAP Mask
Proprietary Name	SleepWeaver élan Nasal CPAP Mask
Legally Marketed (unmodified) Device	SleepWeaver Nasal CPAP Mask (K092362) Common/Usual Name: Nasal CPAP Mask Classification 21 CFR 868.5905 Product Code: BZD Panel: Anesthesiology
Reason for submission	Design Change

Device Description

The SleepWeaver élan Nasal CPAP Mask serves as a mechanism for reliably connecting a patient > 66 lbs (30 kg) diagnosed with sleep apnea to a source of continuous or bi-level positive air pressure needed to maintain an open airway. The nasal mask is placed over a patient's nose and held in place by use of an adjustable elastic headgear. A cloth cushion contacts the patient's face. The mask assembly has an L-shaped tubing swivel connector which is compatible with the industry standard 22 mm air tubing.

Air is supplied to the mask by a CPAP device (which can be standard CPAP or a bi-level 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 exhalation holes.

The SleepWeaver élan can be used in the home environment (single-patient, multi-use) or the institutional environment (multi-patient, multi-use). Cleaning instructions are provided for each environment. Home use calls for washing with warm water and a mild non-abrasive soap. The institutional environment calls for cleaning a validated cleaning agent and a high-level disinfecting agent/process.

The mask features a cloth cushion made of polyester fabric with a polyester/lycra/nylon interface material. The mask exhalation feature is incorporated into the cloth cushion. Attached to the cushion is an L-shaped 22-mm tubing swivel connector that can rotate 360°. The tubing connector can be detached by unscrewing the nut off the threaded connector for ease of cleaning and cushion replacement. The cloth headgear is connected to the mask through slots in the cushion wings. The headgear is removable for ease of cleaning and replacement.

The SleepWeaver élan Nasal CPAP Mask also offers two optional accessories, the Feather Weight tube and the tether strap. The Feather Weight tube is an 18" plastic home-use only extension tube to improve flexibility at the mask connection point. The tether strap, when used, keeps the tubing from resting on the patient's head while he/she sleeps.

Intended Use

The SleepWeaver élan Nasal CPAP Mask is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or Bi-Level therapy. The SleepWeaver élan Nasal CPAP 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).

Contraindications

None.

Predicate Comparison

The SleepWeaver élan Nasal CPAP Mask has the following similarities to the previously cleared predicate device:

Characteristic	SleepWeaver Nasal CPAP Mask
Intended Use	X
Operating Principle	X
Technology	X
Manufacturing Process	X

The fundamental scientific technology of the SleepWeaver élan Nasal CPAP Mask is unchanged from the predicate device (K092362). Circadiance, LLC has made the following changes to the previously cleared SleepWeaver Advance Nasal CPAP Mask to be considered for this submission:

- Cushion Dimensions – The previously cleared cushion dimensions did not provide ideal performance for certain patient populations. As a result, the SleepWeaver élan Nasal CPAP Mask was designed with these dimensional changes to accommodate this customer base.
- Swivel Connector – The previously cleared connector was a straight, swivel connector attached to the cushion with a specified medical-grade tape. The SleepWeaver élan Nasal CPAP Mask utilizes an L-shaped swivel connector that functionally allows for the tubing to rotate a full 360°. The SleepWeaver élan Nasal CPAP Mask swivel connector was designed to be attached with a threaded nut for easier disassembly and reassembly for cleaning and cushion replacement.
- Headgear Dimensions – The previously cleared headgear connected to two wings of the mask and one connection coming down from the forehead. The SleepWeaver élan Nasal

CPAP Mask headgear was designed to remove the forehead connection to avoid pressure being placed on the patient's forehead when using the mask. The SleepWeaver élan Nasal CPAP Mask headgear also features an optional tether strap for positioning of the standard CPAP tube or Feather Weight tube over the patient's head.

- Material – The material of the cushion's elastic interface and the headgear have changed from the previously cleared design. The SleepWeaver élan Nasal CPAP Mask elastic interface is made of a biocompatible textile used in the clothing industry. The SleepWeaver élan Nasal CPAP Mask headgear is made of a biocompatible textile commonly used for CPAP mask headgear.

- Optional Accessories – The previously cleared product was designed without optional accessories. The SleepWeaver élan Nasal CPAP Mask is accompanied by two optional accessories, the Feather Weight tube and the tether strap.

  The Feather Weight tube is an 18" plastic extension tube that connects between the SleepWeaver élan Nasal CPAP Mask and standard CPAP tubing. The Feather Weight tube allows the patient to use a tube that reduces the weight and improves the flexibility at the mask connection point.

  The tether strap is an optional accessory for use with the SleepWeaver élan Nasal CPAP Mask if the patient chooses to position the tubing over his/her head. The tether strap, when used, keeps the tubing from resting on the patient's head while he/she sleeps.

- Labeling – The labeling changes for the SleepWeaver élan Nasal CPAP Mask are as follows:
  - Re-branding and product-specific content changes;
  - Dimensional changes to match the new packaging configuration;
  - Addition of a quick-start guide;
  - Modification of cleaning method warning, instructing the user to only use approved cleaning and disinfecting methods;
  - Feather Weight tube labeling.
- Packaging Changes – The previously cleared product is packaged within an individual box with a peek-through window to visualize the product. The SleepWeaver Élan Nasal CPAP Mask packaging will be dimensionally smaller by volume with no peek through window.

Substantial Equivalency Matrix

Feature	Proposed Device: SleepWeaver élan	Predicate Device: K092362
Intended Use	The SleepWeaver élan Nasal CPAP Mask is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or Bi-Level therapy. The SleepWeaver élan Nasal CPAP 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).	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.
Contraindications	None	None
Product Code	BZD	BZD
Where Used	Home / Hospital	Home / Hospital
Target Population	Sleep Apnea Patients > 66 lbs / 30 kg	Sleep Apnea Patients > 66 lbs / 30 kg
Anatomical Sites	Mask topically interfaces with nose and skin on the face.	Mask topically interfaces with nose and skin on the face.
Human Factors	Usability Testing	Customer preference testing included in the initial submission.
Materials	Headgear: elastane, polyurethane and polyamide, cotton threading Mask: polyester Interface: polyamide/elastane; polyurethane L-Connector: polycarbonate Tube: TPC, EVA Tether Strap: elastane, polyurethane and polyamide, cotton threading	Headgear: Nylon, Acrylic, Polyurethane Mask: Polyester Interface: Nylon/Lycra, Polyurethane Swivel Connector: Polycarbonate
Biocompatibility	New interface material passed ISO 10993-1, -5, and -10 cytotoxicity, sensitization, and irritation tests. Biocompatibility reports of Feather Weight tube material provided by supplier (AccuMED). Biocompatibility reports of new headgear material provided by supplier (AccuMED).	Passed ISO 10993-1, -5, and -10 testing as surface contacting device (cytotoxicity, and irritation tests).
Standards Met	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 5367 ISO 14971 ISO 5356-1 IEC 62366	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 5356-1

Feature	Proposed Device: SleepWeaver élan	Predicate Device: K092362
Compatibility with Other Devices	Tested at pressures from 4 cm H2O up to 20 cm H2O on CPAP and Bi-Level systems. Tested to ISO 5356-1. Feather Weight tube tested to ISO 5356-1, ISO 5367.	Tested at pressures from 4 cm H2O up to 20 cm H2O on CPAP and Bi-Level systems. Tested to ISO 5356-1.
Accessories	Feather Weight Tube Tether Strap	None
Performance	*Pressure drop*: The positive pressure delivered to the patient airway will be within +/-5 cm H20 of the inspiratory pressure setting on the CPAP machine up to 20 cm H20. *Includes expiratory resistance.*	*Pressure drop*: The positive pressure delivered to the patient airway will be within +/-5 cm H20 of the inspiratory pressure setting on the CPAP machine up to 20 cm H20. *Expiratory resistance*: The pressure drop at the patient connection port no greater than 5 cm H2O at a flow of 50 L/min.
	Fixed leakage: The flow rate of the exhalation port at 5 and 20 cm H20. *Inadvertent leak*: The mask inadvertent leak (leak not through the exhalation valve) should be less than 20 l/min at a pressure of 20 cmH2O. *Device Interface*: Waveform testing on Bi-level machines shall include basic waveform data.	*Fixed leakage*: The flow rate of the exhalation port at 5 and 20 cm H20. *Inadvertent leak*: The mask inadvertent leak (leak not through the exhalation valve) should be less than 20 l/min at a pressure of 20 cmH2O. *Device Interface*: Waveform testing on Bi-level machines shall include basic waveform data.

Design Verification

Design verification tests were performed on the Circadiance, LLC SleepWeaver élan Nasal CPAP Mask as a result of the risk analysis and product requirements. Circadiance, LLC has determined that the design presented in this submission meets the safety and effectiveness requirements for a device as required by the FDA. In summary, the device described in this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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APR 2 4 2012

Re: K120757
Trade/Device Name: SleepWeaver elan Nasal CPAP Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: April 4, 2012
Received: April 6, 2012

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

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

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: SleepWeaver élan Nasal CPAP Mask

Indications for Use:

The SleepWeaver élan Nasal CPAP Mask is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or Bi-Level therapy. The SleepWeaver élan Nasal CPAP 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).

Contraindications (if applicable):

None

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheis

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

510(k) Number: K120757