DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 15, 2017

Circadiance, LLC
James Gianoutsos
Manager of Quality Assurance & Regulatory Affairs
1300 Rodi Rd
Turtle Creek, Pennsylvania 15145

Re: K162905
Trade/Device Name: Sleepweaver 3D Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: February 8, 2017
Received: February 9, 2017

Dear James Gianoutsos:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SleepWeaver 3D Nasal Mask Models

Part Number	Description	Color	Size
101496	SleepWeaver 3D Nasal Mask Only, Blue	Blue	N/A*
101516	SleepWeaver 3D Regular Headgear Only	Black	Regular
101517	SleepWeaver 3D Large Headgear Only	Black	Large
101486	SleepWeaver 3D Nasal Mask & Regular Headgear, Blue	Mask: Blue Headgear: Black	Mask: N/A* Headgear: Regular
101491	SleepWeaver 3D Nasal Mask & Large Headgear, Blue	Mask: Blue Headgear: Black	Mask: N/A* Headgear: Large

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162905

Device Name
SleepWeaver 3D Nasal Mask

Indications for Use *(Describe)*
The SleepWeaver 3D Nasal 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 single-patient reuse in the hospital / institutional environment. This mask is to be used on patients greater than 66 lbs (30 kg).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

(as per 21 CFR 807.92)

I. SUBMITTER

Circadiance, LLC
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Phone: (724) 858-2837
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Contact Person: James Gianoutsos
Title: Manager of Quality Assurance & Regulatory Affairs
Date Prepared: October 14, 2016

II. SUBJECT DEVICE

Name of Device: SleepWeaver 3D Nasal Mask
Common or Usual Name: Nasal Mask
Classification Name: Noncontinuous Ventilator (IPPB) (21 CFR 868.5905)
Review Panel: Anesthesiology
Regulatory Class: II
Product Code: BZD
Prior Submissions: None

III. PREDICATE DEVICE

SleepWeaver élan Nasal CPAP Mask, K120757
510(k) Holder: Circadiance, LLC
This predicate has not been subject to a design-related recall

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The SleepWeaver 3D Nasal Mask consists of a fabric cushion, headgear, and a swivel connector. The device is to be used as an interface for Continuous Positive Airway Pressure (CPAP) or Bi-Level therapy. The mask consists of an elastic polyester fabric that provides a seal around the user's nose once positive airway pressure therapy is applied. The mask is held in place with a 4-point adjustable elastic fabric headgear that contains an integrated plastic component to direct the headgear away from the patient's ears. The headgear is attached through slots in the "wings" of the fabric mask to support the mask fit. The mask and headgear are designed to be hand washed in the home (single patient reuse) and the hospital / institutional environment (single patient reuse). Attached to the cushion is an L-shaped swivel connector that can rotate 360 degrees and is compatible with the industry standard 22mm air tubing.

Associated accessories include: (Previously cleared under K120757 and have not been modified)

- Feather Weight Tube
- Tether Strap

V. INDICATIONS FOR USE

The SleepWeaver 3D Nasal 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 single-patient reuse in the hospital / institutional environment. This mask is to be used on patients greater than 66lbs (30 kg).

The Indications for Use statement for the SleepWeaver 3D Nasal Mask device is not identical to the predicate device; however, the differences do not alter the intended use of the device as both the subject and predicate devices have the same intended use for providing an interface for Continuous Positive Airway Pressure (CPAP) or Bi-Level therapy for the home and hospital / institutional environment.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The SleepWeaver 3D Nasal Mask has the following similarities to the previously cleared predicate device, the SleepWeaver élan Nasal CPAP (K120757):

- Substantially equivalent intended use
- Same operating principle
- Similar mask and headgear design
- Similar materials that have passed biocompatibility testing
- Same patient population for patients greater than 66 lbs (30 kg)

The SleepWeaver 3D Nasal Mask has the following differences to the previously cleared predicate device, the SleepWeaver élan Nasal CPAP (K120757):

- The nasal interface material and geometry was changed compared to the predicate device.
- Headgear geometry was changed and includes an integrated plastic component that positions the lower straps below the patient's ears.
- Headgear is provided in two (2) sizes compared to the predicate which only had one (1) size.

Table 1 details a side-by-side comparison of similarities and differences of the SleepWeaver 3D Nasal Mask to the previously cleared predicate device, the SleepWeaver élan Nasal CPAP (K120757)

Table 1: Comparison Table of SleepWeaver 3D Nasal Mask and Predicate

Feature	**Predicate Device:** **SleepWeaver élan (K120757)**	**Subject Device:** **SleepWeaver 3D Nasal Mask**	**Comments**
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 3D Nasal 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 single-patient reuse in the hospital / institutional environment. This mask is to be used on patients greater than 66 lbs (30 kg).	Substantially Equivalent. The inclusion of "single-patient reuse" is a narrower indication to the "multi-patient, multi-use" in the hospital / institutional environment and does not alter the intended use of the device. The device is not approved for reprocessing (cleaning and disinfecting methods) in the clinical setting.
Environment of Use	Home / Hospital	Home / Hospital	Identical
Patient Population	Sleep Apnea Patients > 66 lbs / 30 kg	Sleep Apnea Patients > 66 lbs / 30 kg	Identical
Availability	Prescription Use	Prescription Use	Identical
Contraindications	None	None	Identical
Product Code	BZD	BZD	Identical
Anatomical Sites	Mask topically interfaces with nose and skin on the face.	Mask topically interfaces with nose and skin on the face.	Identical
Sterile/Non-Sterile	Non-Sterile	Non-Sterile	Identical
Therapy Pressure Range	4 – 20 cmH2O	4 – 20 cmH2O	Identical
Connecting Element	22mm L-Shaped Swivel Connector (Removable) Polycarbonate	22mm L-Shaped Swivel Connector (Permanently Secured) Polycarbonate	Substantially Equivalent. An identical 22mm L-Shaped Swivel Connector is utilized in the predicate and subject device. The connector in the subject device is permanently secured.
Device Design (Nasal Interface)	Soft Fabric Seal	Soft Fabric Seal	Substantially Equivalent. The structure of the nasal interface are similar in design and materials. Verification and validation testing was performed and the subject device met all predefined acceptance criteria. Any new materials have been assessed and tested for biocompatibility.
Device Design (Mask Body)	Soft Fabric	Soft Fabric	Substantially Equivalent. Mask Body geometry was changed. Verification and validation testing was performed and the subject device met all predefined acceptance criteria. Materials utilized in the design are identical.

Feature	Predicate Device: SleepWeaver élan (K120757)	Subject Device: SleepWeaver 3D Nasal Mask	Comments
Device Design (Headgear)	4-Point Adjustable Elastic Fabric	4-Point Adjustable Elastic Fabric (Addition of Integrated Plastic Component)	Substantially Equivalent. The "Integrated Plastic Component" positions the lower straps below the patient's ears. Materials utilized in the design are identical.
Accessories	Feather Weight Tube & Tether Strap	Feather Weight Tube & Tether Strap	Identical (Previously cleared under K120757 and has not been modified)
Size (Mask)	Three (3) Sizes (Small, Medium, Large)	One (1) Size	Substantially Equivalent. The subject device has one size of mask due to the nasal interface design and material. Verification and validation testing was performed and the subject device met all predefined acceptance criteria.
Size (Headgear)	One (1) Size	Two (2) Sizes (Regular, Large)	Substantially Equivalent. The subject device has two sizes of headgear to accommodate a broader range of use among the patient population. Verification and validation testing was performed and the subject device met all predefined acceptance criteria.

VII. PERFORMANCE DATA

Non-Clinical Tests

Extensive performance testing was conducted in accordance with ISO 17510:2015 and results were satisfactory to demonstrate substantial equivalence. Performance testing included:

- Fixed Leak Rate (Acceptable per ISO 17510:2015)

Pressure (cmH2O)	4	5	10	15	20
Flow (LPM	18	21	32	41	50

- Pressure Drop (Resistance to Flow) (@50LPM: 0.3cmH2O; @100LMP: 0.5cmH2O)
- CO2 Rebreathing (Acceptable per ISO 17510:2015)
- Sound Pressure (Power Level: 26dBA; Pressure Level @ 1m: 18dBA)
- Reliability (90 wash cycles without damage or loss of function)

The SleepWeaver 3D Nasal Mask has been designed and tested to meet the requirements of the following standards:

1. ISO 14971:2007 Medical Devices - Application of Risk Management to Medical Devices
2. ISO 17510:2015 Medical Devices -- Sleep Apnoea Breathing Therapy -- Masks and Application Accessories
3. ISO 10993-1:2009 Biological Evaluation of Medical Devices - Part 1: Evaluation And Testing within a Risk Management Process
4. ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
5. ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization

The skin contacting portion of the nasal interface material is new and was identified as direct patient contacting, permanent duration (> 30 days) and biocompatibility testing was conducted by applying the principles of biological evaluation of medical devices, in accordance with ISO 10993-1. All tests were successfully completed with acceptable results. Biocompatibility for all other materials utilized in the device is based on the previously cleared predicate device, the SleepWeaver élan Nasal CPAP (K120757).

Clinical Tests

Clinical tests were not required to demonstrate the substantial equivalence of the SleepWeaver 3D Nasal Mask. Product functionality has been adequately assessed by non-clinical tests.

VIII. CONCLUSIONS

Design verification and validation testing was performed on the SleepWeaver 3D Nasal Mask and the subject device met all predefined acceptance criteria. Circadiance has determined that the modifications do not raise different types of safety and effectiveness questions. In summary, the performance and technological characteristics of the SleepWeaver 3D Nasal Mask has been adequately assessed by non-clinical tests and is substantially equivalent to the predicate device, the SleepWeaver élan Nasal CPAP Mask (K120757).