DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 5, 2016

Circadiance, LLC
% Pooja Roychoudhury
Operation Manager
Regulatory & Quality Solutions, LLC
2790 Mosside Blvd, Suite 800
Monroeville, Pennsylvania 15146

Re: K151683
Trade/Device Name: SleepWeaver Advance Pediatric Nasal CPAP Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: March 1, 2016
Received: March 3, 2016

Dear Ms. Roychoudhury:

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 yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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 on last page.

510(k) Number *(if known)*
K151683

Device Name
SleepWeaver Advance Pediatric Nasal CPAP Mask

Indications for Use *(Describe)*
The SleepWeaver Advance Pediatric Nasal Mask is intended to provide an interface for noninvasive Positive Airway Pressure (PAP) ventilation therapy. This mask is intended for single-patient use in the home and single-patient use in the hospital / institutional environment. This mask is to be used on patients between 2 and 7 years of age.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) SUMMARY

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Circadiance, LLC
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Phone: (724) 858-2837
Facsimile: (412) 202-4583
Contact Person: David Groll, CEO, David.Groll@Circadiance.com

Date Originally Prepared: June 19, 2015
Date Revised: April 5, 2016

Name of Device and Name/Address of Sponsor

SleepWeaver Advance Pediatric Nasal CPAP Mask

Common or Usual Name

Vented Nasal Mask

Classification Name

Accessory to Non-Continuous Ventilator, Class II, 21 CFR 868.5905, Product Code: BZD

Predicate Devices

ResMed Ltd., Pixi Pediatric Mask (K102224)

Indications for Use

The SleepWeaver Advance Pediatric Nasal Mask is intended to provide an interface for noninvasive Positive Airway Pressure (PAP) ventilation therapy. This mask is intended for single-patient use in the home and single-patient use in the hospital / institutional environment. This mask is to be used on patients between 2 and 7 years of age.

Description of Device

The SleepWeaver Advance Pediatric Nasal CPAP Mask serves as a mechanism for connecting a pediatric patient between 2 and 7 years of age for whom PAP therapy has been prescribed 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 a tubing swivel connector which is compatible with the industry standard 22 mm air tubing.

Air is supplied to the mask by a therapy device. The patient inhales air from the mask and exhales into the mask where continuous airflow from the therapy device purges the exhaled carbon dioxide from the mask through the mask exhalation holes.

The SleepWeaver Advance Pediatric Nasal CPAP Mask can be used in the home environment (single-patient use) or the hospital/institutional environment (single-patient use).

The mask features a cloth cushion made of a blue polyester fabric with a polyester / nylon / lycra / polyurethane interface material. The mask exhalation feature is incorporated into the cloth cushion. Attached to the cushion is a 22-mm tubing swivel connector that can rotate 360º. The tubing connector can be removed by unwrapping the white medical tape for cleaning and cushion replacement. The cloth headgear is connected to the mask through slots in the cushion wings. The headgear is removable for cleaning and replacement.

The SleepWeaver Advance Pediatric Nasal CPAP Mask product also offers an optional accessory: the Feather Weight tube. The optional SleepWeaver FeatherWeight tube may be used with this mask, but it remains outside the scope of this submission as it has been previously cleared by its inclusion in K120757. The Feather Weight tube is an 18" plastic extension tube compliant to ISO 5356-1 and ISO 5367 that connects between the SleepWeaver Advance Pediatric Nasal CPAP Mask and standard CPAP tubing.

Technological Characteristics

The SleepWeaver Advance Pediatric Nasal CPAP Mask consists of a cloth cushion, headgear, and a swivel connector. Table 1 is provided below which lists additional technological characteristics for the SleepWeaver Advance Pediatric Nasal CPAP Mask as well as a comparison of the described feature to the predicate device.

Table 1: Technological Characteristics and Comparison to the Predicate

Feature	Proposed Device: SleepWeaver Advance Pediatric Nasal CPAP Mask	Predicate Device: ResMed Pixi Pediatric Mask (K102224)	*Equivalence Narrative*
Intended Use	The SleepWeaver Advance Pediatric Nasal Mask is intended to provide an interface for noninvasive Positive Airway Pressure (PAP) ventilation therapy. This mask is intended for single-patient use in the home and single-patient use in the hospital / institutional environment. This mask is to be used on patients between 2 and 7 years of age.	The Pixi Pediatric Mask channels airflow noninvasively to a patient from a continuous positive airway pressure (CPAP) or bilevel device. The Pixi Pediatric Mask is: • To be used by children aged between 2 and 7 for whom continuous positive airway pressure (CPAP) or bilevel therapy has been prescribed. • Intended for single-patient re-use in the home environment and single-patient re-use in the hospital/ institutional environment.	*Same*
Contra-indications	None	None	*Same*
Product Code	BZD	BZD	*Same*
Environment of Use	Hospital, Home	Hospital, Home	*Same*
Patient Population	Pediatric patients between 2 and 7 years of age	Pediatric patients between 2 and 7 years of age	*Same*
Use Case(s)	Single Patient Use	Single Patient Use	*Same*

Components / Accessories	Headgear, Mask, Interface, Swivel Connector, Feather Weight Tube (Optional)	Headgear, Mask frame, Frame nodes, Mask socket, Short tube assembly, Elbow, Plug tether, Plug, Cushion, Vent, Cushion shoulder, Pressure port, Top headgear strap and buckle, Middle headgear strap and buckle, Lower headgear strap and buckle, Quick release clip, Lower headgear arms, 22 mm Swivel	*The SleepWeaver Pediatric and predicate ResMed Pixi both have a nasal mask, adjustable headgear, an interface swivel connection, and a tube assembly. The SleepWeaver Pediatric mask is manufactured from cloth whereas the ResMed Pixi mask has a silicone cushion and a plastic stability feature. The SleepWeaver Pediatric Mask is supported by performance testing; thus it can be concluded that the SleepWeaver Advance Pediatric Nasal CPAP Mask, is substantially equivalent to the predicate device, the ResMed Pixi Pediatric Mask, in regards to this comparison.*
Design			*The SleepWeaver Pediatric Mask and predicate ResMed Pixi are both nasal CPAP masks with adjustable headgear. The SleepWeaver Pediatric mask is manufactured from cloth whereas the ResMed Pixi mask has a silicone cushion and a plastic stability feature. The SleepWeaver Pediatric Mask is supported by performance testing; thus it can be concluded that the SleepWeaver Advance Pediatric Nasal CPAP Mask, is substantially equivalent to the predicate device, the ResMed Pixi Pediatric Mask, in regards to this comparison.*
Materials	Headgear: Nylon, Elastane, Polyurethane Mask: Blue Polyester Interface: Polyester, Nylon, Lycra, Polyurethane Swivel Connector: Polycarbonate	Information not available	*The SleepWeeaver Pediatric Mask and headgear are made of materials used in legally marketed devices (SleepWeaver Advance Nasal CPAP Mask (K092362), SleepWeaver Elan Nasal CPAP Mask (K120757), and SleepWeaver Anew Full Face Mask CPAP (K130481)) and the predicate ResMed Pixi is made of plastic and silicone. The SleepWeaver Pediatric Mask uses biocompatible materials; thus it can be concluded that the SleepWeaver Advance Pediatric Nasal CPAP Mask, is substantially equivalent to the predicate device, the ResMed Pixi Pediatric Mask, in regards to this comparison.*
Therapy Pressure Range	4 – 20 cm H_2O	3 to 20 cm H_2O	*The SleepWeaver Pediatric has a therapy range from 4 to 20 cm H2O whereas he ResMed Pixi has a therapy range from 3 to 20 cm H2O. Since the SleepWeaver Pediatric therapy range is within the therapy range for the ResMed*

<table>
<tr><td></td><td></td><td></td><td>Pixi, it can be concluded that the SleepWeaver Advance Pediatric Nasal CPAP Mask, is substantially equivalent to the predicate device, the ResMed Pixi Pediatric Mask, in regards to this comparison.</td></tr>
<tr><td>Sizing</td><td>1 size</td><td>1 size</td><td>SleepWeaver Pediatric and ResMed Pixi are both sized to accommodate the intended patient population.</td></tr>
<tr><td>Physical Dead Space</td><td>130 mL</td><td>101.7 mL</td><td>The dead space for the SleepWeaver Pediatric is larger than the predicate ResMed Pixi; however, since the SleepWeaver Pediatric mask has exhalation holes and seams that enable continuous purging of the volume of air around the periphery of the mask, it prevents CO_2 build-up. This is supported by the performance testing since the mask has passed the rebreathing tests under ISO 17510-2. Thus it can be concluded that the SleepWeaver Advance Pediatric Nasal CPAP Mask, is substantially equivalent to the predicate device, the ResMed Pixi Pediatric Mask, in regards to this comparison.</td></tr>
<tr><td>A-weighted Sound levels</td><td>Sound Power Level:
26 dBA;
Sound Pressure Level at 1m:
18 dBA</td><td>Not available</td><td>Not applicable</td></tr>
<tr><td>Resistance (pressure drop)</td><td>0.4 cm H2O at 50 L/min;
1.0 cm H2O at 100 L/min</td><td>0.8 cm H2O at 50 L/min;
3.1 cm H2O at 100 L/min</td><td>The resistance for the SleepWeaver Pediatric is lower than the predicate ResMed Pixi; however, a lower pressure drop may be considered preferential as the patient will receive therapy closer to the intended pressure. Thus it can be concluded that the SleepWeaver Advance Pediatric Nasal CPAP Mask, is substantially equivalent to the predicate device, the ResMed Pixi Pediatric Mask, in regards to this comparison.</td></tr>
<tr><td>Carbon Dioxide Washout Profile</td><td>The amount of CO_2 being rebreathed by the patient in all scenarios listed in ISO 17510-2:2009 is less than the maximum allowable percentage increase under normal conditions (20% for 4, 5, and 10 cm H_2O).</td><td>Not available</td><td>The SleepWeaver Pediatric meets ISO 17510-2.</td></tr>
<tr><td>Leak Rate</td><td>
<table>
<tr><th>Pressure (cm H_2O)</th><th>Flow (L/min)</th></tr>
<tr><td>4</td><td>14</td></tr>
<tr><td>5</td><td>16</td></tr>
<tr><td>10</td><td>25</td></tr>
<tr><td>15</td><td>33</td></tr>
<tr><td>20</td><td>40</td></tr>
</table>
</td><td>
<table>
<tr><th>Pressure (cm H_2O)</th><th>Flow (L/min)</th></tr>
<tr><td>3</td><td>18</td></tr>
<tr><td>7</td><td>28</td></tr>
<tr><td>12</td><td>36</td></tr>
<tr><td>16</td><td>43</td></tr>
<tr><td>20</td><td>49</td></tr>
</table>
</td><td>The leak rate is lower than the predicate ResMed Pixi. Since the leak rate of the SleepWeaver Pediatric mask is greater than a patient would exhale per minute and the SleepWeaver Pediatric mask passed the rebreathing tests under ISO 17510-2, it can be concluded that the SleepWeaver Advance Pediatric Nasal CPAP Mask, is substantially equivalent to</td></tr>
</table>

			the predicate device, the ResMed Pixi Pediatric Mask, in regards to this comparison.
Applied Standards	ISO 14971, ISO 10993-1, 10993-5, ISO 10993-10, ISO 5356-1, IEC 62366, ISO 5367, ISO 17510-2	ISO 10993-1	*Not applicable*

Non-Clinical Testing Summary:

Bench top testing for the SleepWeaver Advance Pediatric Nasal CPAP Mask included the following tests or evaluations:

- Product performance;
  - Fixed leak rate per ISO 17510-2;
  - Resistance to flow per ISO 17510-2;
  - CO2 rebreathing testing per ISO 17510-2;
  - Physical dead space; and
  - Headgear attachment;
- Reliability/Cleaning;
- Fit evaluation and anthropometric analysis; and
- Simulated use case;
- Biocompatibility;
  - Patient contact Duration: Permanent
  - Gas Pathway (External Communicating) Components: Swivel connector, mask body material, nasal interface, and internal surface of the oral interface. The materials in these components have been used in legally marketed devices (SleepWeaver Advance Nasal CPAP Mask (K092362), SleepWeaver Elan Nasal CPAP Mask (K120757), and SleepWeaver Anew Full Face Mask CPAP (K130481)).
  - Surface Contact (Skin) Components: Headgear/mask wings and external surface of the oral interface. The materials in these components have been used in legally marketed devices (SleepWeaver Advance Nasal CPAP Mask (K092362), SleepWeaver Elan Nasal CPAP Mask (K120757), and SleepWeaver Anew Full Face Mask CPAP (K130481)).

The packaging of the SleepWeaver Advance Pediatric Nasal CPAP mask uses the same packaging and is stored in the same way as other legally marketed devices (SleepWeaver Advance Nasal CPAP Mask (K092362)).

Clinical Data

Use of the SleepWeaver Advance Pediatric Nasal CPAP Mask is supported by bench testing and is sufficient to demonstrate substantial equivalence to the ResMed Pixi Pediatric Mask.

Substantial Equivalence (Conclusion)

The new device, the SleepWeaver Advance Pediatric Nasal CPAP Mask, is substantially equivalent to the predicate device, the ResMed Pixi Pediatric Mask (K102224):

- it has the same intended use;
- it has the same patient population;
- it has similar technological characteristics;
- it has similar performance characteristics; and
- it does not raise new questions of safety and effectiveness

Thus it can be concluded that the SleepWeaver Advance Pediatric Nasal CPAP Mask, is substantially equivalent to the predicate device, the ResMed Pixi Pediatric Mask.