March 30, 2018

snapCPAP
% Paul Dryden
snapCPAP c/o ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K172335
Trade/Device Name: Bleep DreamPort
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: March 1, 2018
Received: April 1, 2017

Dear Paul Dryden:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K172335

Device Name

Bleep™ DreamPort

Indications for Use *(Describe)*

The Bleep™ DreamPort nasal adhesive mask is intended to provide an interface from a Continuous Positive Airway Pressure (CPAP) or bi-level system. The mask to be used by adult patients (>66 lbs. / 30 kg.) for whom positive airway pressure has been prescribed. The mask is for single-patient reuse in the home, hospital/institutional environment.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date:	19-Mar-18
Company:	snapCPAP 143 Harrison Pond Dr. Pittsboro, NC 27312
Official Contact:	Stuart Heatherington – Founder and CEO Tel - 919-619-7170
Proprietary or Trade Name:	Bleep™ DreamPort
Common/Usual Name:	CPAP Nasal adhesive mask
Classification Name:	21 CFR 868.5905, Class II Procode – BZD Non-continuous ventilator (IPPB)
Predicate Device:	K073638 – Resmed – Swift LT
Reference Device:	K112404 – Ventus Medical – ProVent

Device Description:
The Bleep™ DreamPort nasal adhesive mask is similar to standard nasal pillow CPAP mask for use with patients using CPAP and bi-level equipment for the treat of OSA.

The Bleep™ DreamPort nasal adhesive mask is comprised of 2 sub-assemblies:

- Nasal Port assembly
- Airflow management assembly

The device uses single use foam tape to create the seal at the nostrils. This allows the interface to be used without head gear. There is a reusable interface which connects the nasal adhesive to the circuit of the CPAP equipment. It includes integrated exhalation ports.

We included the following reference device K102502Ventus Medical – ProVent as it utilizes foam tape to seal at the nostrils. The ProVent has the same intended use as the subject device but deploys a different technology of creating positive pressure and both devices require an effective seal created by flexible adhesive tape at the nostrils to function.

Indications for Use:
The Bleep™ DreamPort nasal adhesive mask is intended to provide an interface from a Continuous Positive Airway Pressure (CPAP) or bi-level system. The mask to be used by adult patients (>66 lbs. / 30 kg.) for whom positive airway pressure has been prescribed. The mask is for single-patient reuse in the home, hospital/institutional environment.

Patient Population:
For adults (>66 lbs. / >30 kg.).

Environment of Use:
Home, hospital/institutional environment

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Contraindications:
The contraindications are the same as the predicate and include the standard cautions and warnings typical of CPAP and bi-level positive pressure device patient interfaces and are included in the labeling.

Table 1 – Comparison to the Predicate

Attributes	**Predicate** **Resmed Swift LT** **K073638**	**Bleep™ DreamPort** **Proposed Device**
Indications for Use	The Swift LT channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system. The Swift LT is: * to be used by adult patients (> 66 lbs. /30 kg.) for whom positive airway pressure has been prescribed. * intended for single-patient re-use in the home environment and multi-patient re-use in the hospital / institutional environment.	The Bleep™ DreamPort nasal adhesive mask is intended to provide an interface from a Continuous Positive Airway Pressure (CPAP) or bi-level system. The mask to be used by adult patients (>66 lbs. / 30 kg.) for whom positive airway pressure has been prescribed. The mask is for single-patient reuse in the home, hospital/institutional environment.
Patient Population	Adults > 66 lbs. / > 30 kg.	Adults > 66 lbs. / > 30 kg.
Environment of Use	Single-patient reuse in the home environment Multi-patient re-use in the hospital/institutional environment	Single-patient reuse in the home, hospital/institutional environment
Duration of Use	Single patient, multi-use Multi-patient, re-use	Single patient, multi-use
Prescriptive	Yes	Yes
Features		
Available sizes	Multiple pillow sizes	One size
Components	Nasal pillow Frame with exhalation port Hose with swivel adapter Head gear to assist with holding in place	Nasal pillow Frame with exhalation port Hose with swivel adapter Adhesive strips to hold in place and seal
Incorporates exhalation port and connecting tube	Yes	Yes
Nasal pillow interface	Silicone pillows	Channels connecting to frame and Foam tape to create seal and hold in place Reference K102404 Ventus Medical - ProVent
Frame with exhalation port	Yes	Yes
Head gear	Yes	No
Cleaning method	Soap and water	Soap and water
Materials	Nasal pillow – silicone Frame – rigid material	Nasal interface – Foam Tape Frame – Flexible and rigid material

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Attributes	**Predicate** **Resmed Swift LT** **K073638**	**Bleep™ DreamPort** **Proposed Device**
Therapy Pressures and compatibility with CPAP equipment	4 to 20 cm H_2O Used with equipment which provide pressures within the defined therapy pressure range.	4 to 15 cm H_2O Used with equipment which provide pressures within the defined therapy pressure range.
Operating Temperature Storage Temperature	+5 to 40°C (+41 to 104°F) -20 to + 60°C (-4 to 140°F)	+10 to 40°C (+50 to 104°F) -20 to +60°C (-4 to 140°F)
Non-clinical Performance Testing		
ISO 17510-2 - CPAP Mask testing		
CO_2 washout profile Tested per ISO 17510-2 Acceptance < 20% increase from baseline	Not tested	**Pressure** **$ETCO_2$% at mask (% increase)** 4 cm H_2O 5.3 (2%) 5 cm H_2O 5.3 (1%) 10 cm H_2O 5.15 (-2%)
Exhaust flow Average (Lpm) at various pressure settings in cmH_2O)	4 – 19.5 8 – 25.5 12 – 32.1 16 – 37.8 20 – 42.8	4 – 20.4 8 – 29.2 12 – 35.7 16 – 41.3 20 – 46.0
Pressure Drop (cmH_2O) at various flow rates	50 Lpm - 2.0 cmH_2O 100 Lpm – 8.4 cmH_2O	50 Lpm – 0.9 cmH_2O 100 Lpm – 4.4 cmH_2O
Dead space (interface only not including the hose)	22 mL	16 mL
Drop test	N/A	No visual damage
Cleaning of reusable tubing and exhalation valve portion		90 cleaning cycles Differences in performance testing between pre- and post-conditioning was < 10%
Effects of Aging	N/A	Differences in performance testing between pre- and post-conditioning was < 10%
Shelf-life	Not stated	6 months
Biocompatibility –ISO 10993-1 Patient profile	Externally communicating Tissue And Surface Contact (pillow) Skin Permanent duration	Externally communicating Tissue And Surface Contact (foam tape) Intact Skin Permanent duration
Testing	N/A	Cytotoxicity Sensitization Irritation Leachable / Extractable Risk Based Assessment with MOS >1

510(k) Summary

Substantial Equivalence Discussion

The Bleep™ DreamPort nasal adhesive mask is viewed as substantially equivalent to the predicate device because:

Indications –

- The Bleep™ DreamPort nasal adhesive mask is intended to provide a patient interface for application of positive pressure therapy. The mask is to be used as an accessory for use with CPAP or Bi-level positive pressure systems intended for application of CPAP or bi-level therapy.
- Similar to the predicate Resmed Swift LT – K073638

Patient Population –

- The masks are for patients > 66 lbs. / > 30 kg. for whom positive airway pressure therapy has been prescribed.
- Similar to the predicate Resmed Swift LT – K073638.

Environment of Use –

- The masks are intended for use in the home, hospital/institutional environment
- Similar to the predicate Resmed Swift LT – K073638.

Technology –

- The design of subject device is similar in that they both have a soft nasal interface with a rigid frame and exhalation port with extension hose to connect to the CPAP equipment and its own circuit.
- The subject device utilizes an already cleared exhalation valve and hose. The nasal patient interface is a flexible set of nostril inserts that are then held in place with adhesive foam tape.
- The Bleep™ DreamPort does not require head gear to hold it in place as it uses foam tape whereas the predicate is held in place with head gear.
- Testing has demonstrated that the subject device performed equivalent to the predicate when tested according to ISO 17510:2015: Medical Devices -- Sleep apnoea breathing therapy -- Masks and application accessories.

Discussion -

The difference in the subject device is that the attachment to the user to hold the device in place is flexible foam tape vs. soft, silicone pillows which are “pressurized” to be held in place with a head strap. Bench and clinical testing demonstrated the subject device as substantially equivalent to the predicate.

Clinical testing

A user study was performed where comparison of performance between the predicate and the subject was performed over 2 nights. The objectives were to evaluate the effectiveness of the subject device seal under different CPAP pressure settings when used with a humidifier and compare leak rates and mean AHI during use. The subject device was found to be substantially equivalent in performance.

Non-clinical performance testing

Biocompatibility / Materials –

The materials in patient contact have been tested they are characterized as:

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- External Communicating (Indirect gas pathway), Tissue / Bone / Dentin communicating, Duration of Use – permanent (> 30 days)

And

- Surface Contact, Skin, Duration of Use – permanent (> 30 days)
- The materials in patient contact were tested per ISO 10993-1 were found to be non-cytotoxic, non-irritating, non-sensitizing, and with a margin of safety > 1.

The following tests and the results were acceptable.

- Cytotoxicity – ISO 10993-5:2009
- Sensitization – ISO 10993-10:2010
- Irritation (for surface contact materials) – ISO 10993-10:2010
- Leachable and Extractables – polar and non-polar
- Risk based assessment

Bench / Performance testing -

Comparative performance testing the tests included:

- ISO 17510-2:2015: Medical Devices — Sleep apnea breathing therapy - Masks and application accessories. These tests included:
  - Exhaust Flow
  - Pressure Drop
  - CO_2 washout
- Biocompatibility of Materials
- Cleaning
- Mechanical Drop test
- Effects of Aging on Performance
- Environmental Testing / Shelf-life

The results demonstrated that the device performance was met after conditioning and was substantially equivalent to the predicate.

Substantial Equivalence Conclusion

The performance testing demonstrates that the subject device is substantially equivalent to the predicate device.