August 3, 2018

CPAPNEA Medical Supply
Sal Hakim
Owner and manager
10443 N Cave Creek Road, Suite 110
Phoenix, Arizona 85020

Re: K181219
Trade/Device Name: OptiPillows EPAP Mask
Regulation Number: 21 CFR 874.3900
Regulation Name: Nasal Dilator
Regulatory Class: Class I
Product Code: LWF
Dated: April 27, 2018
Received: May 7, 2018

Dear Sal Hakim:

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 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,

Michael J. Ryan -S

for Malvina Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat 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)*
K181219

Device Name
OptiPillows EPAP Mask

Indications for Use *(Describe)*
OptiPillows EPAP Mask is intended for use during sleep to alleviate snoring. It is intended for the adult population with snoring only.

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.

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

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510(k) Summary
For
Optipillows EPAP Mask
K181219

Submission Sponsor and correspondence 807.92(a)(1)

CPAPNEA MEDICAL SUPPLY
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Contact Person: Sal T. Hakim, Ph.D.

Date Prepared: August 2, 2018

Device Name: OptiPillows EPAP Mask 807.92(a) (2)
Common/usual name: EPAP Nasal Pillows Mask
Classification name: Nasal Dilator
Review Panel: Ear Nose and Throat
Regulation Number: 874.3900
Product Code: LWF
Device Class: I

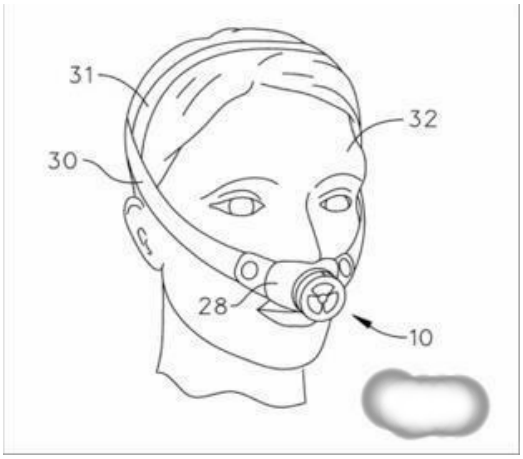
- Recognized Consensus Standards:
  ISO 10993-1, Biological evaluation of medical devices– Part 1: Evaluation and testing within a risk management process.
  ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for In Vitro Cytotoxicity.
  ISO 10993-06 Biological evaluation of medical devices – Part 6: Tests for local effects after implantation.
  ISO 109930-10 Biological evaluation of medical devices – Part 10: Tests for Irritation and Skin Sensitization.

Predicate Device: 807.92(a) (3)
InVent Snoring Device, K120665, 03/05/2012.

Device Description: 807.92(a) (4)

OptiPillows EPAP mask is a nasal dilator device for alleviation of snoring. The EPAP mask is a reusable device. The EPAP mask has nasal pillows that fit against the nostrils similar to the ones used in several nasal pillow CPAP masks. The EPAP mask has a one-way valve attached to it that allows air to flow freely without resistance during inspiration. The mask is held in place with adjustable head straps connected to the sides of the mask (Figure below). During expiration, the air is redirected through a narrow opening, on the side of the valve. The expiratory opening creates resistance to airflow, thus increasing the back pressure in the nose, mouth, and upper airways. The increase in back pressure during expiration prevents the collapse of the upper airways, alleviating airway obstruction. The level of back pressure can be adjusted to the patient comfort by turning a rotating sleeve/collar to open or close the expiratory opening on the side of the valve. The adjustable expiratory resistance improves the comfort and safety for the user and facilitates adaptation to the EPAP mask.

The EPAP mask is a small device and is used like a CPAP mask, but does not require using a power supply, a CPAP machine or tubing that restricts movement of the patient during sleep.



10 = one way valve 30, 31 = head straps 28 = body of the mask

Intended Use: 807.92(a) (5)

OptiPillows EPAP Mask is intended for use during sleep to alleviate snoring. It is intended for the adult population with snoring only.

A physician should be consulted for evaluation of obstructive sleep apnea or other respiratory disorders, if snoring is accompanied by any of the following symptoms:

- *Frequent excessive daytime sleepiness*
- *Periods of not breathing (also known as apnea), as observed by bed- partners*
- *Awaking short of breath, choking or gagging*
- *Do not use if pain or discomfort results*
- *Do not continue use if ineffective*

Contraindications:

- *A history of heart disease*
- *Being substantially overweight*
- *Not for use by infants or children*

Principles of operation:

The patient wears the EPAP mask during sleep in a manner similar to using a CPAP mask. The head straps on the EPAP mask are adjusted so that the nasal pillows provide a comfortable seal against the nostrils. The two-way valve on the EPAP mask allows air to flow in with minimal resistance during inspiration. However, during expiration, air flow is redirected through a narrow opening on the side of the valve. The resistance to airflow during expiration creates back pressure in the upper airways thus alleviating upper airway obstruction and snoring. The level of back pressure that the valve creates can be adjusted to suit the comfort of the patient, by turning a rotating sleeve that regulates the size of the expiratory opening. There is a small door-jam on the valve to prevent the valve from closing completely. The patient is required to breathe through the nose for the mask to work, however breathing through the mouth occasionally is acceptable and does not pose a problem. OptiPillows EPAP mask is substantially equivalent to the predicate device Theravent. The materials used in the construction of the EPAP mask are same materials that are used in many nasal pillow CPAP masks, with respect to form, material, construction, safety, and toxicity. The two-way valve that is attached to the mask works in a substantially equivalent manner to the predicate device in operation, but allows for adjustable expiratory resistances, making it more adaptable to most people who intend to use it. Unlike the predicate device which is intended for one-time use, the EPAP mask can be used repeatedly for many times.

Comparison with predicate devices: 807.92(a) (6)

	OptiPillows EPAP Mask	InVent Snoring Device
K number	K181219	K120665
Classification	1	1
Product Code	LWF	LWF
Regulation #	874.3900	874.3900
Safe	Yes	Yes

Patient Contact Material	Silicone and fabric	Adhesive
Nasal Dilator	Yes	Yes
Non-Sterile	Yes	Yes
Intended Use	Anti-Snoring	Anti-Snoring
Mechanism of operation	Positive Pressure during expiration by a resistance valve	Positive Pressure during expiration by a resistance valve
A single patient use	Yes	Yes
One Time use	Reusable	One time use
OTC	Yes	Yes
Expiratory Resistance	Adjustable	Fixed

Intended Use: Like the predicate device, Optipillows EPAP Mask is intended to alleviate snoring. It is intended for the adult population with snoring only.

Substantial Equivalence discussion: 807.92 (b)

OptiPillows EPAP Mask is substantially equivalent to the predicate device in terms of intended use, and the principle of operation and level of expiratory pressure that it generates, and does not raise new questions concerning safety and effectiveness. The EPAP mask is held in place with fabric straps, while the predicate device InVent is held in place with adhesive material pasted on the skin around the nostrils to create an air seal. In contrast, the EPAP mask creates an air seal my adjusting the tensions on the headgear to secure the nasal pillows against the nostrils. The nasal pillows on the EPAP mask are similar in shape and material as several nasal pillow CPAP masks and do not raise new questions concerning safety or toxicity. The EPAP mask allows patients to adjust the level of the expiratory resistance according to their comfort. The expiratory resistance can be set on low to facilitate getting used to the mask and c a n be increased to alleviate their upper airway obstruction. Like the predicate device, the EPAP mask is an expiratory resistance device and generates expiratory pressure comparable to the predicate device. The performance testing showed that that the pressure generated by the EPAP mask over the available range of resistances is substantially equivalent to the predicate device. The nasal pillows of the EPAP mask are made of silicone material, and the head straps are made of the material used commonly in the CPAP industry. These materials are used in many nasal pillow CPAP masks cleared by the FDA.

Non-clinical tests: Both devices use similar technologies, namely expiratory resistance to cause

an increase in the pressure in the upper airway during expiration. In a series of benchtop laboratory studies where the OptiPillows was set at 50%, both devices were found to function equally well under conditions of steady unidirectional flow, bidirectional cyclic flow, and low and high tidal volume. The expiratory resistance on OptiPillows can be easily adjusted to any desired levels to accommodate differences in patients and to improve patient comfort. In contrast, InVent Snoring Device has a fixed resistance that may not be easily tolerated by all patients. With the expiratory resistance fully open, the pressure in the back of the mouth is very low; it almost feels normal. When the expiratory resistance is about 50% closed, it is comparable to InVent. The adjustable resistance on the EPAP valve allows the patient to adjust the resistance to minimal level until they become more acclimated to the device. The primary goal of the OptiPillows EPAP mask is to alleviate upper airway obstruction and snoring as best as possible while breathing comfortably.

Clinical study:

We asked patients who had used the EPAP mask to give us feedback on their experience with the EPAP mask. We used a clinical questionnaire designed specifically to assess the usability of the EPAP mask over the available range of expiratory resistance valve settings. The questionnaire consisted of a series of 13 questions about use of the EPAP mask, and about its benefits. We also used the Epworth Sleepiness Scale (ESS) questionnaire to assess sleep and daytime functioning. ESS is a self-administered questionnaire with 8 questions where patients rate their chances of dozing off or falling asleep during eight activities, and is used to assess the patients' daytime sleepiness. ESS is widely used in sleep medicine, in clinical and research settings. There were 2 groups of patients.

Group 1 consisted of patients who have been using the EPAP mask for more than 6 months We provided the questionnaire to 39 patients, but only 29 responded; 21 men (32 to 68 yrs old) and 8 women (36 to 64 yrs old). The median BMI in males was 27 and in females was 26. Only one patient who could not get used to the mask responded (#21) and returned the questionnaire. It is likely that among the 10 who did not respond, some could not get used to the mask for one reason or the other or simply were not interested in helping us. We asked them to fill out the clinical questionnaire about the usability and the benefits of the EPAP mask. We also asked them to fill out the Epworth Sleepiness Scale (ESS) questionnaire to see how they are doing with regards to their sleep and daytime functioning. The patients were looking to treat their snoring problems. Some of the patients who received the questionnaire did not return them to us. The questionnaire was specifically designed to allow us to evaluate the clinical usability of the EPAP mask and to give us feedback about any potential problems, such as difficulty with the use of the EPAP mask, or with understanding how to use the mask, or how to adjust the expiratory resistance. Furthermore it provided us with feedback if they liked using the EPAP mask, and if it provided some benefits. These patients were also asked to fill out the ESS questionnaire after using the EPAP mask.

Group 2 consisted of 18 new patients who were interested for the first time in trying the EPAP mask to treat their snoring. These patients were self-reported habitual snorers and never been diagnosed with sleep disordered breathing by a healthcare professional. They were simply

interested in doing something about their snoring. We asked them to fill out ESS questionnaire prior to using the EPAP mask, and 30 to 60 days after using the EPAP Mask to see if the EPAP mask had any impact on their sleep. We also asked them to fill out the clinical questionnaire to get feedback about the usability and the benefits of the EPAP Mask. Out of 18 patients, only 13 responded and completed the questionnaires: four females (46 to 59 yrs old) and 9 males (30 to 66 yrs old). Median BMI in males was 28 and in females was 24.

Results: The results of our clinical questionnaire from both groups revealed that the EPAP mask is user friendly, easy to use, and safe. Users, with the help of their bed partners, also reported feeling an improvement in their snoring. There were no concerns expressed by the users about the safety of the EPAP mask and there were no reports of any adverse events among the patients who responded to the survey other than having difficulty falling asleep during the first week of using the EPAP mask. The EPAP mask is well liked by many patients after an initial one week orientation period, but may not be ideal for every user; some just cannot get used to it and refuse to use it. The device also helped to some extent in improving daytime functioning after 1-2 months use, as seen by the slight decrease in daytime sleepiness score as measured using the Epworth Sleepiness Scale (8.7±0.7 to 6.2±1.2). The minimally clinically important difference of ESS has recently been estimated to be between -2 and -3 [Patel, S., et al., (2018). American Journal of Respiratory and Critical Care Medicine, 961-962.].

Biocompatibility: OptiPillows EPAP Mask is made of materials that have been used for many years in nasal pillow CPAP masks that are FDA cleared (such as K063036, K102502, K090244, K103434, K112271, K112489). The materials are standard medical grade materials and have been time tested without problems or risk to patients. The pillows that fit against the nostrils are made of medical grade silicone material, the same materials used in several nasal pillow CPAP masks. The ABS (Acrylonitrile butadiene styrene) thermoplastic material used to mold the valve is approved by the FDA for use in dental and medical devices, is used in many CPAP masks without problems and is safe for use, nevertheless, it does not come in contact with the skin. The fabric material is used in many CPAP masks, including, nasal pillow, and full face masks and raise no concerns or risks. The results of the biocompatibility testing revealed no concern in terms of material safety for the user. There is no concern regarding toxicity and safety of the materials utilized in manufacturing.

Shelf Life and Reuse: Accelerated aging testing was performed to support a 6 month shelf life. Different parts of the mask were inspected after accelerated aging. There was no significant visual or material degradation in the different components. Additionally, simulated airflow testing after the aging demonstrated that the performance of the device was not affected. The device can be cleaned daily with mild soap without concern of material or performance degradation.

Conclusion: 807.92 (b) (3)

OptiPillows EPAP Mask is an expiratory resistance device and is substantially equivalent to the predicate devices in intended use and principle of operation.