February 21, 2020

Bryggs Medical, LLC
Geoffrey Sleeper
President
34910 Commerce Way
Avon, Ohio 44011

Re: K191728
Trade/Device Name: ULTepap
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices For Snoring And Intraoral Devices For Snoring And Obstructive Sleep Apnea
Regulatory Class: Class II
Product Code: OHP
Dated: January 23, 2020
Received: January 24, 2020

Dear Geoffrey Sleeper:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Michael Ryan
Division Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*

Device Name
ULTepap ™

Indications for Use (*Describe)*
ULTepap ™ is indicated for use in the treatment of mild to moderate Obstructive Sleep Apnea (OSA) in adults> 66lbs.

Type of Use *(Select one or both, as applicable)*
☒Prescriptlon Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

5.1 Submission Owner and Correspondent

Submission Owner

BRYGGS
Medical, LLC
34910 Commerce
Way
Suite 2
Avon, OH 44011
Phone: 440-937-8181
Fax: 440-695-0913

Submission Correspondent

Geoffrey Sleeper
BRYGGS
Medical, LLC
34910 Commerce
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Suite 2
Avon, OH 44011
Phone: 216-870-6990
Email: geoffrey.sleeper@gmail.com

5.2 Date Summary Prepared

June 26, 2019

5.3 Device Trade Name

ULTepap™

5.4 Device Common Name

ULTepap™

5.5 Device Classification Name

Expiratory resistance valve, intranasal for obstructive sleep apnea; OHP; Classification at 21 CFR 872.5570; Class II

5.6 Legally Marketed Device To Which The Device Is Substantially Equivalent

The ULTepap™ is substantially equivalent to Ventus Medical's Provent cleared under K102404 on December 2, 2010 and InnoMed Healthscience's Bongo cleared under K180619 on August 16, 2018. BRYGGS is also introducing reference devices for the purpose of making some technological comparisons. Reference devices similar to the ULTepap™ are the SNAPP Sleep Apnea Therapy cleared under K034053 on June 24, 2004 and the P-B Adam Circuit Nasal Pillows cleared under K900164 on January 26, 1990.

5.7 Description of The Device

The ULTepap™ is a single patient, reusable device intended to treat mild to moderate OSA. It is comprised of a soft silicon rubber body that contains a pair of bi-resistance airflow cartridges, has flanges to attach headgear, and has nasal pillows to interface with the nares. The device is held in place on the patients face by means of a common CPAP mask headgear which is provided in the packaging. The device creates a therapeutic level of positive pressure on exhalation by means of the airflow cartridges that allow air to enter the patient's upper airway without resistance on inhalation and created resistance to airflow on exhalation. The airflow cartridges are comprised of a cylinder and a flexible thin-walled shell which are aligned with the nasal pillows to allow unimpeded inspiration and partially restricted expiration to create the appropriate level of therapeutic back pressure. The thin-walled shells collapse on inspiration and re-inflate on expiration and create a restricted area for expiration by inflating and sealing the inner diameter of the cylinder, forcing expiration through a series of channels molded in the cylinder.

5.8 Intended Use of the Device

The ULTepap™ is indicated for use in the treatment of mild to moderate Obstructive Sleep Apnea (OSA) in adults > 66 lbs.

5.9 Technological Characteristics

The proposed ULTepap™ has similar technical characteristics to the predicate Ventus Corp Provent Sleep Apnea Therapy device, cleared under K102404, and the Innomed Healthscience, Inc. Bongo, cleared under K180619. A comparison of technological characteristics is presented in Table 5.1.

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Attribute	**Proposed Device:** ULTepap™ Intranasal device	**Primary Predicate Device:** Provent® (K102404)	**Secondary Predicate Device:** Bongo (K180619)
Indications for Use	ULTepap™ is indicated for use in the treatment of mild to moderate Obstructive Sleep Apnea (OSA) in adults > 66 lbs.	Provent® Sleep apnea Therapy is indicated for the treatment of obstructive sleep apnea (OSA)	The Bongo Rx is indicated for use in the treatment of mild to moderate obstructive sleep apnea (OSA) in adults > 66 lbs.
Principles of Operation - Physical configuration	Soft silicon rubber body that contains a pair of bi-resistance airflow cartridges, with flanges to attach headgear and with integrated nasal pillows to interface with the nares	A pair of adhesives-backed thin patches containing flap valves that adhere to the underside of the nares	A pair of connected silicon rubber inserts that are attached to flap valves, with flanges to attach headgear. The inserts interface inside the nares

Features - How the devices are secured to the patient	The assembly is held in place by a conventional CPAP headgear	Held in place by means of the adhesive	The nasal inserts may be used with or without conventional headgear, depending on patient preference
Features - Duration of use	Usable device for a maximum of three months	One-night use only	Usable device for a maximum of three months
Materials	BODY & SHELL - Liquid Silicone rubber (LSR) LIM 6040 CYLINDER – Polycarbonate resin Type: PC Poly Grade:ML-1020R ADHESIVE – RTV 108 Acetoxy Sealant	*A pair of adhesive backed thin patches containing flap valves that adhere to the underside of the nares Material not known.	*INSERTS & FLAP VALVES – Not known FLAP CASES – Not known
Positive Pressure range	4.2 -20.3 cmH2O	5.7 -21.2 cmH2O	1.1 – 4.5 cmH2O
Patient Population	adults > 66 lbs.	Adults	adults > 66 lbs.
Environment of use	Home or sleep lab use at night while sleeping	Home or sleep lab use at night while sleeping	Home or sleep lab use at night while sleeping
Use Type	Single Patient, reusable	Single patient, one night only	Single Patient, reusable
Sealing method	CPAP headgear that holds the nasal pillows against the nares	Adhesive that sticks the valves	Optional CPAP headgear that helps keep the nasal pillows in the nares
Features	Multiple sizes, single resistance	One size, single resistance	Multiple sizes, single resistance

5.10 Non-Clinical Testing

The following non-clinical tests were performed on device that underwent full manufacturing:

- Back pressure comparison demonstrating the ULTepap™ creates back pressure in the same range as two predicate devices.
- Air flow cartridge fatigue while testing the cleaning impact on material integrity.
- Comfort evaluation study.
- Accelerated Aging Test to determine acceptable shelf life claims.
- Inhalation resistance testing
- Cleaning validation
- Vibration/drop testing
- Environmental Testing

5.11 Biocompatibility

The following biocompatibility tests were completed:

- *In-Vitro* Cytotoxicity Study by Elution Method (ISO 10993-5:2009(E)
- Skin Sensitization Maximization Test (ISO 10993-10:2010(E))
- Intracutaneous Reactivity Test (ISO 10993-10:2010(E)
- The materials used in the proposed device are certified by the vendor to be identical in formulation and processing to the reference device, K034053

5.12 Clinical Testing

No clinical testing was performed in association with this submission.

5.13 Conclusions

The results of the comparison of design, materials, intended use, and technological characteristics demonstrate that the device is as safe and effective as the legally marketed predicate devices.