July 5, 2019

Sleepnet Corporation
% Paul Dryden, Consultant
ProMedic, LLC
131 Bay Point Dr NE
St. Petersburg, Florida 33704

Re: K190254
Trade/Device Name: Mojo 2 Full Face Vented Mask, Veraseal 3 Full Face Vented Mask, V3 Full Face Vented Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: June 5, 2019
Received: June 6, 2019

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. 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

James Lee, PhD
Assistant 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 on last page.

510(k) Number *(if known)*

K190254

Device Name

Mojo 2 Full Face Vented Mask
Veraseal 3 Full Face Vented Mask
V3 Full Face Vented Mask

Indications for Use *(Describe)*

The Sleepnet Mojo 2 Full Face Vented Mask, Veraseal 3 Full Face Vented Mask, and V3 Full Face Vented Mask are intended to be used with positive airway pressure devices, such as CPAP or bi-level, operating at or above 3 cm H_2O.

The masks are to be used on adult patients (>30 kg.) for whom positive airway pressure therapy has been prescribed.

Veraseal 3	Disposable single use (hospital/institutional) Single patient, multi-use up to 7 days (hospital/institutional)
V3	Single patient, multi-use (home)
Mojo 2	Single patient, multi-use (home or hospital/institutional)

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
5-July 19

Sleepnet Corporation
5 Merrill Industrial Drive
Hampton, NH 03842
Tel - 603-758-6625
Fax - 603-758-6699

Official Contact: Jennifer Kennedy – Director of Regulatory and Quality

Proprietary or Trade Name: Mojo 2 Full Face Vented Mask
Veraseal 3 Full Face Vented Mask
V3 Full Face Vented Mask

Common/Usual Name: Patient interface for CPAP

Classification Code/Name: BZD – non-continuous ventilator (IPPB)
CFR 868.5905

Device: Mojo 2 Full Face Vented Mask
Veraseal 3 Full Face Vented Mask
V3 Full Face Vented Mask

Predicate Devices: K120463 – Sleepnet Veraseal and Mojo Full Face mask
Reference Devices: K121692 - MiniMe 2 nasal

Device Description:
The Sleepnet Mojo 2, Veraseal 3 and V3 Full Face mask are provided with an exhalation elbow and anti-asphyxia (AAV) valve.

The subject of this submission is:

- Slight redesign of the shape of the masks but no appreciable differences as the identical exhalation elbow and anti-asphyxia valve (AAV)
- Add an additional size, ex-large, mask to the product line
- Support useful life of the V3 and Mojo 2 up to 6 months as a single patient, multi-use mask

Veraseal 3 is intended as a Disposable single use (hospital/institutional) and as a Single patient, multi-use up to 7 days (hospital/institutional)

V3 is intended as a Single patient, multi-use (home)

Mojo 2 is intended as a Single patient, multi-use (home or hospital/institutional

Indications for Use:
The Sleepnet Mojo 2 Full Face Vented Mask, Veraseal 3 Full Face Vented Mask, and V3 Full Face Vented Mask are intended to be used with positive airway pressure devices, such as CPAP or bi-level, operating at or above 3 cm H_2O.

The masks are to be used on adult patients (>30 kg.) for whom positive airway pressure therapy has been prescribed.

510(k) Summary

Veraseal 3 –
Disposable single use (hospital/institutional)
Single patient, multi-use up to 7 days (hospital/institutional)

V3 –
Single patient, multi-use (home)

Mojo 2 –
Single patient, multi-use (home or hospital/institutional

Patient Population: For adults (>30 kg)

Environment of Use: Home or hospital / institutional environments

Substantial Equivalence Discussion:

We discuss the major attributes for demonstrating substantial equivalence below. These refer to the table below this discussion.

The Sleepnet Veraseal 3, V3, and Mojo 2 Full face mask are viewed as substantially equivalent to the predicate device because:

Indications –

- The Veraseal 3, V3, and Mojo 2 masks are intended to be used with positive airway pressure devices, such as CPAP or bi-level operating at or above 3 cm H_2O.
  The masks are to be used on adult patients (>30 kg) for whom positive airway pressure therapy has been prescribed.
- Identical to Sleepnet masks – K120463

Patient Population –

- The masks are to be used on adult patients (>30kg) for whom positive airway pressure therapy has been prescribed.
- Identical to Sleepnet – K120463

Environment of Use –

- The masks are intended for use in the home or hospital/institutional environment.
- Identical to predicates – Sleepnet – K120463

Technology –

- Identical technology to – Sleepnet mask – K120463

Non-clinical testing

Biocompatibility –

- The materials in patient contact are identical to predicate devices.

510(k) Summary

Bench testing
We compared performance for:

- Internal Volume / Dead space
- Pressure drop
- Anti-asphyxia valve pressure testing
- CO_2 washout
- Simulated life testing post-cleaning
- Mechanical drop test
- Meets ISO 17510 testing

Differences –
There are no differences between the predicate and the proposed devices which would raise new safety concerns. The subject devices are found to be substantially equivalent to the identified predicate device.