June 27, 2024

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

Re: K241520
Trade/Device Name: Mojo 2 Full Face Non-Vented Mask; Mojo 2 Full Face AAV Non-Vented Mask; Veraseal 3 Full Face Non-Vented Mask; Veraseal 3 Full Face AAV Non-Vented Mask
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: May 29, 2024
Received: May 29, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

John S. Bender -S

Digitally signed by John S. Bender -S
Date: 2024.06.27 12:44:58 -04'00'

for Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241520

Device Name

Mojo 2 Full Face Non-Vented Mask
Mojo 2 Full Face AAV Non-Vented Mask
Veraseal 3 Full Face Non-Vented Mask
Veraseal 3 Full Face AAV Non-Vented Mask

Indications for Use *(Describe)*

The Sleepnet Mojo 2 and Veraseal 3 Full Face Non-Vented and AAV Non-Vented Masks are intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators that have adequate alarms and safety systems for ventilator failure, and which are intended to administer positive pressure ventilation. The mask will be offered in a disposable version and a multi-use version. It is intended for use on adult patients (>30 kg), who are appropriate candidates for noninvasive ventilation.

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

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.

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

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Date Prepared:	June 27, 2024
Sponsor:	Sleepnet Corporation 5 Merrill Industrial Drive Hampton, NH 03842 Tel - 603-758-6625
Sponsor Contact:	Jennifer Kennedy - Director of Regulatory & Quality
Submission Correspondent:	Paul Dryden ProMedic, LLC
Proprietary or Trade Name:	Veraseal 3 Full Face Non-Vented Mask Veraseal 3 Full Face AAV Non-Vented Mojo 2 Full Face Non-Vented Mask Mojo 2 AAV Non-Vented Full-Face Mask
Common/Usual Name:	Patient Interface
Classification Name:	Continuous Ventilator 21 CFR 868. 5895
Product Code:	CBK
Predicate Device:	Veraseal 3 Full Face Non-Vented Mask Veraseal 3 Full Face AAV Non-Vented Mojo 2 Full Face Non-Vented Mask Mojo 2 AAV Non-Vented Full-Face Mask
510(k):	K190533
Common/Usual Name:	Patient Interface
Classification Name:	Continuous Ventilator 21 CFR 868.5895
Product Code:	CBK

Device Description:
The Sleepnet Mojo 2 and Veraseal 3 are full face mask used with non0invasive ventilation. They are available in multiple sizes and in a Non-Vented style with an elbow and Non-Vented with elbow and anti-asphyxia (AAV) valve.

The subject of this submission is:

- The Mojo 2 subject devices include a new contradiction and warning, which was not included in the predicate device – K190533.

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

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

Principle of Operation:
The subject device provides a seal around the nose and acts as a patient interface for positive pressure air delivery.

Indications for Use:
The Sleepnet Mojo 2 and Veraseal 3 Non-Vented and AAV Non-Vented Full Face Masks are intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators that have adequate alarms and safety systems for ventilator failure, and which are intended to administer positive pressure ventilation. The mask will be offered in a disposable version and a multi-use version. It is intended for use on adult patients (>30 kg), who are appropriate candidates for noninvasive ventilation.

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

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

Patient Population: For adult patients (>30 kg).

Environments of use: Home or hospital / institutional environments.

Substantial Equivalence Discussion

The table below compares the key features of the subject devices with the identified predicate – K190533. The subject and predicate devices are identical in every way – the only difference between the devices within this submission is the addition of a contraindication and warning.

Indications for Use –
The indications for use are identical for the subject device when compared to the predicate device – K190533.
Discussion – The indications for use are identical.

Technology and construction –
The technology and principle of operation is identical for the subject device when compared to the predicate device – K190533.
Discussion – Both the subject and predicate device have identical principles of operation.

Environment of Use –
The environments of use are identical to the predicate device – K190533.
Discussion – The environments of use are identical.

Patient Population –
The patient population is identical to the predicate device – K190533.
Discussion – The subject and predicate device patient populations are identical.

Non-Clinical Testing Summary –

Bench testing –
No new performance testing was conducted on the subject device, since the device designs are identical to the predicates.

Biocompatibility –
The medical devices in their final finished form are identical to the Mojo 2 Full Face Non-Vented mask, Mojo 2 AAV Non-Vented Full Face mask, Veraseal 3 Full Face Non-Vented Mask and the Veraseal 3 Full Face AAV Non-Vented mask (previously marketed devices under K190533) in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

Discussion of Differences

Differences between Subject and Predicate Device
The Mojo 2 subject devices include a new contradiction and warning, which was not included in the predicate device – K190533. There are no other differences between the subject and predicate devices.

In March 2024, Sleepnet underwent a voluntary recall (Event 94169) of its masks that contained magnets. Specifically, the Mojo 2 subject devices were part of this recall. This recall was initiated based on information obtained from post market surveillance indicating a possible risk to patients and anyone in close physical contact with the subject device, having an active medical implant or metallic implant that can be impacted by the magnetic field. The magnets in these masks provide a quick and easy method of attaching and detaching the mask from the headgear. However, when a magnet comes into close proximity to certain medical implants or metallic implants, it could interfere with the performance or the position of the implant. This could potentially lead to serious injury or death. Therefore, Sleepnet intends to update its contraindications and warnings as a proactive measure to provide additional safety information to patients and healthcare professionals. To date, there have been no Medical Device Reports associated with the Sleepnet masks with magnets.

Modifications to Labeling:
The Mojo 2 Full Face Non-Vented mask and the Mojo 2 AAV Non-Vented Full Face mask Instructions for Use (IFU) have been updated with the following new contraindication and revised warning statement.

New Contraindication
Do not use this mask if you or anyone (example: household members, bed partners, caregivers, etc.) in close physical contact with your mask has an active medical implant or metallic implant that will interact with magnets. Implant examples include, but are not limited to, pacemakers, implantable cardioverter defibrillators (ICD), neurostimulators, aneurysm clips, metallic stents, ocular implants, insulin/infusion pumps, cerebral spinal fluid (CSF) shunts, embolic coils, metallic splinter, implants

to restore hearing or balance with implanted magnets (such as cochlear implants), flow disruption devices, contact lenses with metal, dental implants, metallic cranial plates, screws, burr hole covers, bone substitute device, magnetic metallic implants/electrodes/valves placed in upper limbs, torso, or higher, etc. If you have any questions regarding the implant, consult your physician or the manufacturer of your implant.

Updated Warning
Magnets are used in the mask and headgear clips with a field strength of 380mT. With the exception of the devices identified in the contraindication, ensure that the mask is kept at least 6 inches (approx.16 cm) away from any other medical implants or medical devices that can be impacted by the magnetic fields to avoid possible effects from localized magnetic fields. This applies to you or anyone in close physical contact with your mask.

Discussion of Differences
Apart from the contraindication and updated warning there are no other differences.

Substantial Equivalence Conclusion
The Sleepnet Mojo 2 and Veraseal 3 Full Face Non- Vented and AAV Non-Vented Masks have identical indications, technological characteristics and principles of operation and performance that the proposed device is substantially equivalent to the predicate.

Attributes	Subject – Mojo 2, Veraseal 3 Full Face Non-Vented and AAV Non-Vented Mask	Predicate – Mojo 2, Veraseal 3 Non-Vented and AAV Non-Vented Full Face Mask	Explanation of Differences
510(k)	TBD	K190533	
Product Classification **CFR**	CBK Continuous ventilator CFR 868.5895	CBK Continuous ventilator CFR 868.5895	Identical
List of Devices	Mojo 2 Full Face Non-Vented mask Mojo 2 Full Face AAV Non-Vented mask Veraseal 3 Full Face Non-Vented mask Veraseal 3 Full Face AAV Non-Vented mask	Mojo 2 Non-vented Full Face mask Mojo 2 AAV Non-vented Full Face mask Veraseal 3 Non-vented Full Face mask Veraseal 3 AAV Non-vented Full Face mask	Identical
Indications for Use	The Sleepnet Mojo 2 and Veraseal 3 Full Face Non- Vented and AAV Non-Vented Masks are intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators that have adequate alarms and safety systems for ventilator failure, and which are intended to administer positive pressure ventilation. The mask will be offered in a disposable version and a multiuse version. It is intended for use on adult patients (>30 kg), who are appropriate candidates for noninvasive ventilation. **Veraseal 3 –** Disposable single use (hospital/institutional) Single patient, multi-use up to 7 days (hospital/institutional) **Mojo 2 –** Single patient, multi-use (home or hospital/institutional)	The Sleepnet Mojo 2 and Veraseal 3 Non- Vented and AAV Non-Vented Full Face Masks are intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators that have adequate alarms and safety systems for ventilator failure, and which are intended to administer positive pressure ventilation. The mask will be offered in a disposable version and a multiuse version. It is intended for use on adult patients (>30 kg), who are appropriate candidates for noninvasive ventilation. **Veraseal 3 –** Disposable single use (hospital/institutional) Single patient, multi-use up to 7 days (hospital/institutional) **Mojo 2 –** Single patient, multi-use (home or hospital/institutional)	Identical
Patient Population	Adult (>30 kg)	Adult (>30 kg)	Identical

Attributes	Subject – Mojo 2, Veraseal 3 Full Face Non-Vented and AAV Non-Vented Mask	Predicate – Mojo 2, Veraseal 3 Non-Vented and AAV Non-Vented Full Face Mask	Explanation of Differences
Patient type	Patients who are appropriate candidates for non-invasive ventilation	Patients who are appropriate candidates for non-invasive ventilation	Identical
Prescriptive	Yes	Yes	Identical
Environment of Use	The masks are intended for use in the home or hospital/institutional environment.	The masks are intended for use in the home or hospital/institutional environment.	Identical
Duration of Use	**Veraseal 3** Disposable, single patient use Single patient, multi-use up to 7 days **Mojo 2** Single patient, multi-use	**Veraseal 3** Disposable, single patient use Single patient, multi-use up to 7 days **Mojo 2** Single patient, multi-use	Identical
Principle of Operation	Provides a seal over the face (nose and mouth) to allow for delivery of pressurized air from a non-invasive ventilator. Mask is used with circuits that include an exhalation port for flushing out exhaled CO_2. The AAV Non-Vented version comes with an anti-asphyxia valve as an additional safety feature. This valve helps in flushing out exhaled CO_2 during Fault condition (e.g. power failure) The device is passive until connected to the ventilator.	Provides a seal over the face (nose and mouth) to allow for delivery of pressurized air from a non-invasive ventilator. Mask is used with circuits that include an exhalation port for flushing out exhaled CO_2. The AAV Non-Vented version comes with an anti-asphyxia valve as an additional safety feature. This valve helps in flushing out exhaled CO_2 during Fault condition (e.g. power failure) The device is passive until connected to the ventilator.	Identical
Therapy Pressure	Greater than 3 cm H_2O Typically determined by the equipment to which it is attached.	Greater than 3 cm H_2O Typically determined by the equipment to which it is attached.	Identical
Anatomical site	Face (seals around nose and mouth)	Face (seals around nose and mouth)	Identical
User Interface to administer therapy	Masks have a standard 22mm ID connection (compliant with ISO 5356-1) that connects to 22mm ventilator circuits.	Mask has a standard 22mm ID connection (compliant with ISO 5356-1) that connects to 22mm ventilator circuits.	Identical

Attributes	Subject – Mojo 2, Veraseal 3 Full Face Non-Vented and AAV Non-Vented Mask	Predicate – Mojo 2, Veraseal 3 Non-Vented and AAV Non-Vented Full Face Mask	Explanation of Differences
Contraindications	New Contraindication (Mojo 2 only) Do not use this mask if you or anyone (example: household members, bed partners, caregivers, etc.) in close physical contact with your mask has an active medical implant or metallic implant that will interact with magnets. Implant examples include, but are not limited to, pacemakers, implantable cardioverter defibrillators (ICD), neurostimulators, aneurysm clips, metallic stents, ocular implants, insulin/infusion pumps, cerebral spinal fluid (CSF) shunts, embolic coils, metallic splinter, implants to restore hearing or balance with implanted magnets (such as cochlear implants), flow disruption devices, contact lenses with metal, dental implants, metallic cranial plates, screws, burr hole covers, bone substitute device, magnetic metallic implants/electrodes/valves placed in upper limbs, torso, or higher, etc. If you have any questions regarding the implant, consult your physician or the manufacturer of your implant.	None	New as per recall event #94169 .
Warnings	Updated Warning Magnets are used in the mask and headgear clips with a field strength of 380mT. With the exception of the devices identified in the contraindication, ensure that the mask is kept at least 6 inches (approx.16 cm) away from any other medical implants or medical devices that can be impacted by the magnetic fields to avoid possible effects from localized magnetic fields.	Unchanged from K190533	Updated as per recall event #94169.

Attributes	Subject – Mojo 2, Veraseal 3 Full Face Non-Vented and AAV Non-Vented Mask	Predicate – Mojo 2, Veraseal 3 Non-Vented and AAV Non-Vented Full Face Mask	Explanation of Differences
	This applies to you or anyone in close physical contact with your mask.		
Useful life	**Veraseal 3** – Single patient use disposable - 7 days **Mojo 2 –** Single patient use - 6 months	**Veraseal 3** – Single patient use disposable - 7 days **Mojo 2 –** Single patient use - 6 months	Identical
Non-sterile	Yes	Yes	Identical
Cleaning methods	Mild Soap (such as Ivory) and water Isopropyl alcohol	Mild Soap (such as Ivory) and water Isopropyl alcohol	Identical