June 15, 2024

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

Re: K241469
Trade/Device Name: iQ 2 Nasal Vented Mask; Phantom 2 Nasal Vented Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: May 23, 2024
Received: May 24, 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,

Rachana Visaria -S

Rachana Visaria, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241469

Device Name
iQ 2 Nasal Vented Mask and Phantom 2 Nasal Vented Mask

Indications for Use *(Describe)*
The iQ 2 Nasal Vented Mask and Phantom 2 Nasal Vented Mask are intended to be used with positive airway pressure devices, such as CPAP or bi-level, operating at 3 cmH2O to 30 cmH2O. The masks are to be used on adult patients (>30 kg) for whom positive airway pressure therapy has been prescribed. The masks are intended for single-patient multi-use in the home, hospital or institutional environment.

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

15-Jun-24

Sponsor:
Sleepnet Corporation
5 Merrill Industrial Drive Tel - 603-758-6625
Hampton, NH 03842

Sponsor Contact: Jennifer Kennedy – Director of Regulatory and Quality

Submission Correspondent: Paul Dryden
ProMedic, LLC

Proprietary or Trade Name: iQ 2 Nasal Vented Mask and Phantom 2 Nasal Vented Mask

Common/Usual Name: Patient interface for CPAP

Regulation Number: 21CFR 868.5905
Regulation Code: Non-continuous ventilator (IPPB)
Product Code: BZD

Device: iQ 2 and Phantom 2 Nasal Vented Mask

Predicate Device: K211274 – Sleepnet iQ 2 and Phantom 2 Nasal Mask
Regulation Number: 21CFR 868.5905
Regulation Code: Non-continuous ventilator (IPPB)
Product Code: BZD

Device Description:
The Sleepnet iQ 2 and Phantom 2 Nasal Vented masks are nearly identical to the Predicate Sleepnet iQ 2 and Phantom 2 Nasal Mask (K211274).

The subject of this submission is:
• Addition of a contraindication related to magnets on the iQ 2 Nasal Vented Mask and Phantom 2 Nasal Vented Mask
• Update to the warning related to magnets on the iQ 2 Nasal Vented Mask and Phantom 2 Nasal Vented Mask

Indications for Use:
The iQ 2 Nasal Vented Mask and Phantom 2 Nasal Vented Mask are intended to be used with positive airway pressure devices, such as CPAP or bi-level, operating at 3 cmH_2O to 30 cmH_2O. The masks are to be used on adult patients (>30 kg) for whom positive airway pressure therapy has been prescribed. The masks are intended for single-patient multi-use in the home, hospital or institutional environment.

Patient Population: For adults (>30 kg)

Environment of Use: Home or hospital / institutional environments

Substantial Equivalence Discussion:

The Sleepnet iQ 2 and Phantom 2 Nasal Vented masks are viewed as substantially equivalent to the predicate device because:

Indications –

- We have updated the device name and removed "or above" in the Indications for Use which are similar.
- Similar to the predicate – K211274.

Patient Population –

- The masks are to be used on adult patients (>30 kg) for whom positive airway pressure therapy has been prescribed.
- Identical to the predicate – K211274.

Environment of Use –

- The masks are intended for use in the home or hospital/institutional environment.
- Identical to the predicate – K211274.

Technological Characteristics –

- Identical technology to the predicate – K211274.

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.

Discussion **–** The performance test results from the predicate device were leveraged for the subject device.

Biocompatibility –

There has been no change in the materials – the subject and predicate device utilize the same materials.

Discussion – The biocompatibility test results from the predicate device were leveraged for the subject device.

Reprocessing –

There has been no change in the reprocessing – the subject and predicate device utilize the same reprocessing instructions.

Discussion – The reprocessing test results from the predicate device were leveraged for the subject device.

We have demonstrated that the proposed device is equivalent to the predicate, K211274.

Table of Comparison to Predicate

Attributes	**Subject –** **iQ 2 Nasal Vented Mask and** **Phantom 2 Nasal Vented Mask**	**Predicate –** **iQ 2/ Phantom 2 Nasal Mask**	**Explanation of Differences**
510(k)	K241469	K211274	
Product Classification CFR	BZD CFR 868.5905	BZD CFR 868.5905	Identical
Indications for Use	The iQ 2 Nasal Vented Mask and Phantom 2 Nasal Vented Mask are intended to be used with positive airway pressure devices, such as CPAP or bi-level, operating at 3 cmH2O to 30 cmH2O. The masks are to be used on adult patients (>30 kg) for whom positive airway pressure therapy has been prescribed. The masks are intended for single-patient multi-use in the home, hospital or institutional environment.	The iQ 2/ Phantom 2 Nasal Mask is intended to be used with positive airway pressure devices, such as CPAP or bi-level, operating at or above 3 cm H2O. The mask is to be used on adult patients (>30kg) for whom positive airway pressure therapy has been prescribed. The mask is intended for single- patient multi-use in the home, hospital or institutional environment.	Similar Removed “or above” for clarity
Patient Population	Adult (>30 kg)	Adult (>30 kg)	Identical
Patient type	Patients for whom positive airway pressure therapy has been prescribed	Patients for whom positive airway pressure therapy has been prescribed	Identical
Prescriptive	Yes	Yes	Identical
Principle of Operation	Device provides a seal over the nose to allow for delivery of pressurized air from a positive airway pressure device. Device has an exhalation port for flushing out exhaled CO_2. The device is passive until connected to the positive pressure device.	Device provides a seal over the nose to allow for delivery of pressurized air from a positive airway pressure device. Device has an exhalation port for flushing out exhaled CO_2. The device is passive until connected to the positive pressure device.	Identical
Contraindication and Warnings	<u>New Contraindication</u> 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	There were no contraindications in K211274.	New as per recall event #94169 Original K211274 labeling available in Section 006_Labeling.

	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. <u>Updated Warning</u> 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. For instance, the functioning of implants may change, or implants may move within the body due to magnetic attraction/repulsion. This applies to you or anyone in close physical contact with your mask.	<u>Magnet Warning</u> Magnets are used in the swivel frame/tube set and the headgear clips. The magnetic field strength is 380 mT. Ensure that the magnets are kept at least 2.25 inches (6 cm) away from any active medical implant or medical device that can be impacted by the magnetic field (e.g., pacemaker, defibrillators, neurostimulators, cochlear implants, hearing aids) to avoid possible effects from localized magnetic fields	
Therapy Pressure Range	3 cm H_2O to 30 cm H_2O.	3 cm H_2O to 30 cm H_2O.	Identical
Anatomical site	Face (seals around nose)	Face (seals around nose)	Identical
User Interface to administer therapy	Masks have a standard 22mm connection that connects to 22mm CPAP/bi-level circuits.	Masks have a standard 22mm connection that connects to 22mm CPAP/bi-level circuits.	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	Single patient, multi-use	Single patient, multi-use	Identical

Attributes	**Subject – iQ 2/ Phantom 2 nasal vented mask**	**Predicate – iQ 2/ Phantom 2 nasal mask**	**Explanation of Differences**
Useful life	Mask cushion – 1 month Swivel frame/tube set – 3 months Headgear and magnetic clips – 6 months	Mask cushion – 1 month Swivel frame/tube set – 3 months Headgear and magnetic clips – 6 months	Identical
Shelf life	5 years.	5 years.	Identical
Non-sterile	Yes	Yes	Identical
Cleaning methods	Mild Soap (such as Ivory) and warm water	Mild Soap (such as Ivory) and warm water	Identical
Available sizes	1	1	Identical
Shape	Identical	Identical	Identical
Incorporates an Exhaust port	Yes	Yes	Identical

Components of the mask	• Mask cushion
	  ○ Mask shell
	  ○ Gel bladder
	• Headgear
	Swivel frame/tube set (tubing assembly)
		• Mask cushion
		  ○ Mask shell
		  ○ Gel bladder
		• Headgear
		Swivel frame/tube set (tubing assembly)
			Identical

Shell design	Soft	Soft	Identical

<table>
<tr><th>Attributes</th><th>Subject –
iQ 2/ Phantom 2 nasal vented mask</th><th>Predicate –
iQ 2/ Phantom 2 nasal mask</th><th>Explanation of Differences</th></tr>
<tr><td>Patient Contact per ISO 10993-1</td><td>Skin contact, Skin and Externally Communicating with tissue (air pathway)
Permanent contact</td><td>Skin contact, Skin and Externally Communicating with tissue (air pathway)
Permanent contact</td><td>Identical</td></tr>
<tr><td>Exhaust Flow</td><td>
<table>
<tr><th rowspan="2">Pressure (cm H2O)</th><th colspan="2">Exhaust flow (lpm)</th></tr>
<tr><th>iQ 2</th><th>Phantom 2</th></tr>
<tr><td>4</td><td>18.2</td><td>18.9</td></tr>
<tr><td>8</td><td>26.3</td><td>27.5</td></tr>
<tr><td>12</td><td>34.3</td><td>35.2</td></tr>
<tr><td>16</td><td>39.6</td><td>39.2</td></tr>
<tr><td>20</td><td>44.0</td><td>45.3</td></tr>
<tr><td>24</td><td>49.8</td><td>50.6</td></tr>
<tr><td>28</td><td>53.4</td><td>55.3</td></tr>
<tr><td>30</td><td>55.6</td><td>56.8</td></tr>
</table>
</td><td>
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<tr><th rowspan="2">Pressure (cm H2O)</th><th colspan="2">Exhaust flow (lpm)</th></tr>
<tr><th>iQ 2</th><th>Phantom 2</th></tr>
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<tr><td>28</td><td>53.4</td><td>55.3</td></tr>
<tr><td>30</td><td>55.6</td><td>56.8</td></tr>
</table>
</td><td>Identical</td></tr>
<tr><td>Dead space</td><td>iQ 2 –
Mask – 47.3 ml
Tubing – 68.33 ml

Phantom 2 –
Mask – 30.7 ml
Tubing – 68.33 ml</td><td>iQ 2 –
Mask – 47.3 ml
Tubing – 68.33 ml

Phantom 2 –
Mask – 30.7 ml
Tubing – 68.33 ml</td><td>Identical</td></tr>
<tr><td>Resistance to flow (pressure drop)</td><td>
<table>
<tr><th rowspan="2">Flow rate (lpm)</th><th colspan="2">Pressure drop (cm H2O)</th></tr>
<tr><th>iQ 2</th><th>Phantom 2</th></tr>
<tr><td>50</td><td>0.45</td><td>0.45</td></tr>
<tr><td>100</td><td>2.05</td><td>2.06</td></tr>
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<tr><td>100</td><td>2.05</td><td>2.06</td></tr>
</table>
</td><td>Identical</td></tr>
<tr><td>Sound pressure and Sound power level</td><td>iQ 2 -
Sound pressure - 30.32 dB
Sound power - 33.33 dB

Phantom 2 -
Sound pressure – 30.49 dB Sound power – 33.50 dB</td><td>iQ 2 -
Sound pressure - 30.32 dB
Sound power - 33.33 dB

Phantom 2 -
Sound pressure – 30.49 dB Sound power – 33.50 dB</td><td>Identical</td></tr>
</table>

Substantial Equivalence Conclusion:

The iQ 2 Nasal Vented Mask and Phantom 2 Nasal Vented Mask have identical indications, technological characteristics and principles of operation and performance to the predicate and performance testing demonstrates that the subject device is substantially equivalent to the predicate.