January 10, 2022

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

Re: K211274
Trade/Device Name: iQ 2 and Phantom 2 Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: December 10, 2021
Received: December 13, 2021

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,

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)*
K211274

Device Name
iQ 2 and Phantom 2 Nasal Mask

Indications for Use *(Describe)*
The iQ 2 and 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 to 30 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.

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

10-Jan-22

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

Sponsor Contact: Jennifer Kennedy – Director of Regulatory and Quality

Submission Correspondent: Paul Dryden
ProMedic, LLC

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

Common/Usual Name: Patient interface for CPAP

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

Device: iQ 2 and Phantom 2 Nasal Mask

Predicate Device: K021534 - Sleepnet iQ Nasal mask
Regulation Number: 21CFR 868.5905
Regulation Code: Non-continuous ventilator (IPPB)
Product Code: BZD
Regulatory Class: II

Device Description:
The Sleepnet iQ 2 and Phantom 2 Nasal masks are patient interfaces for use with positive pressure equipment, i.e., CPAP and bi-level. They incorporate an exhaust port in the shell.

The 2 styles are similar:

- Same patient population and Indications for Use
- Same headgear
- Same headgear connector components
- Same tubing assembly
- Same materials and manufacturing processes

They differ only in:

- Mask shell shape
- Gel cushion shape

Indications for Use:
The iQ 2 and 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 H_2O to 30 cmH_2O. The mask is to be used on adult patients (>30 kg) 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.

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 masks are viewed as substantially equivalent to the predicate device because:

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

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

Environment of Use –
- The masks are intended for use in the home or hospital/institutional environment.
- Similar to the predicate.

Technological Characteristics –
- Similar technology to the predicate.

Non-clinical testing

Biocompatibility –
- Some materials have been identified as identical to similar Sleepnet masks and a material certification provided. For the head strap, following testing were performed:
    - ISO 10993-5:2009 – Cytotoxicity MEM
    - ISO 10993-10:2010 – Sensitization and Irritation.

Performance bench testing
The following performance tests were performed as per ISO 17510-2- Medical Devices - Sleep Apnoea Breathing Therapy - Masks And Application Accessories:
- Internal Volume / Dead space
- Exhaust flow
- Resistance to Flow

Mechanical Drop test
ISO 5356-1 ISO 5356-1:1996 - Anaesthetic and Respiratory Equipment -- Conical Connectors -- Part 1: Cones And Socket

Table of Comparison to Predicate

Attributes	**Subject – iQ 2 and Phantom 2 nasal mask**	**Predicate – iQ nasal mask**	**Explanation of Differences**
510(k)	K211274	K021534	- -
Product Classification CFR	BZD CFR 868.5905	BZD CFR 868.5905	Identical
Indications for Use	The iQ2 and 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 H_2O to 30 cmH_2O. 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.	The Sleepnet Corporation iQ® nasal mask is intended to be used with positive airway pressure devices, such as CPAP, operating at or above 3 cm H_2O for the treatment of adult obstructive sleep apnea. The mask is intended for single patient use, or multiple patient use with proper high level disinfection. The mask may be used in the home or hospital/institutional environment. The mask is to be used on adult patients (>30kg) for whom positive airway pressure therapy has been prescribed.	Similar The predicate included single patient and multiple patient use, whereas the subject devices will be single patient use only.
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

Attributes	**Subject – iQ 2 and Phantom 2 nasal mask**	**Predicate – iQ nasal mask**	**Explanation of Differences**
Therapy Pressure	3 cm H_2O to 30 cm H_2O.	3 cm H_2O to 20 cm H_2O.	Similar. The lower limits are identical. The upper limits is determined by the equipment to which the mask is attached. Most CPAP machines today have a higher upper limit of 30 cm H_2O
Anatomical site	Seals around nose	Seals around nose	Identical
User Interface to administer therapy	Masks have a standard 22mm connection that connects to 22mm CPAP/bi-level circuits.	Masks has a standard 22mm connection that connects to 22mm CPAP/bi-level circuits.	Identical
Contraindications	None	None	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 Multi-patient, multi-use	Similar Removed multi-patient use for the subject device.
Useful life	Mask cushion – 1 month Swivel frame/tube set – 3 months Headgear and magnetic clips – 6 months	6 months	Components of the subject device will be offered individually as replacements
Shelf life	5 years	No shelf life stated.	Similar 5 year shelf life has been validated for the subject devices.
Non-sterile	Yes	Yes	Identical
Cleaning methods	Mild Soap and warm water	Mild detergent and warm water	Cleaning method is identical to the predicate as previously cleared
Features			
Available sizes	1	1	Identical
Shape	Similar	Similar	Similar

Attributes	**Subject – iQ 2 and Phantom 2 nasal mask**	**Predicate – iQ nasal mask**	**Explanation of Differences**
Incorporates an Exhaust port	Yes	Yes	Identical

Components of the mask	• Mask cushion
	  ○ Mask shell with vent holes
	  ○ Gel bladder
	• Headgear
	• Swivel frame/tube set (tubing assembly)
		• Mask shell
		• Gel bladder
		• Vented elbow
		• Headgear
		• Tubing
			Similar

Shell design	Soft	Soft	Similar
Patient Contact per ISO 10993-1	Skin contact, Skin and Externally Communicating with tissue (air pathway) Permanent contact	Skin contact, Skin and Externally Communicating with tissue (air pathway) Permanent contact	Some materials are identical and the headgear is new and tested per ISO 10993-1
Performance Characteristics			
Exhaust flow (vent flow)	**Pressure ($cm H_2O$)** / **Exhaust flow (lpm)** – **iQ 2** / **Phantom 2** 4 / 18.2 / 18.9 8 / 26.3 / 27.5 12 / 34.6 / 35.2 16 / 39.6 / 39.2 20 / 44.0 / 45.3 24 / 49.8 / 50.6 28 / 53.4 / 55.3 30 / 55.6 / 56.8	**Pressure ($cm H_2O$)** / **Exhaust flow (lpm)** 4 / 22.1 8 / 28.7 12 / 37.1 16 / 44.3 20 / 49.8 24 / 54.2 28 / 58.7 30 / 60.4	Similar. The exhaust flow of the predicate is slightly higher. There are no acceptance criteria for exhaust flow in ISO 17510:2015.
Dead space	**iQ 2** – Mask – 47.3 ml Tubing – 68.33 ml **Phantom 2** – Mask – 30.7 ml Tubing – 68.33 ml	Mask – 68.6 ml Tubing – 62 ml	Similar

<table>
<tr><td rowspan="3">Resistance to flow (pressure drop)</td><td>Flow rate (lpm)</td><td colspan="2">Pressure drop (cm H_2O)</td><td>Flow rate (lpm)</td><td>Pressure drop (cm H_2O)</td><td rowspan="3">The subject devices have a lower pressure drop compared to the predicate. There are no acceptance criteria for pressure drop in ISO 17510:2015. The pressure drop for a device is disclosed in the labeling This aids therapists in deciding the appropriate pressure setting based on the desired therapy pressure for the patient.</td></tr>
<tr><td></td><td>iQ 2</td><td>Phantom 2</td><td></td><td></td></tr>
<tr><td>50
100</td><td>0.443
2.043</td><td>0.447
2.057</td><td>50
100</td><td>0.86
3.06</td></tr>
<tr><td>Sound pressure and Sound power level</td><td colspan="3">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 colspan="2">Sound pressure – 29.90 dB
Sound power – 37.90 dB</td><td>Similar.
There are no acceptance criteria specified in ISO 17510:2015 for sound levels.</td></tr>
<tr><td>Operating Range</td><td colspan="3">Operating Temperature: Do not expose the mask to temperatures above 122˚F (50˚C).</td><td colspan="2">Operating Temperature: Do not expose the mask to temperatures above 122˚F (50˚C).</td><td>Similar</td></tr>
</table>

Substantial Equivalence Conclusion:

The iQ2 and Phantom 2 Nasal masks have similar indications, technological characteristics and principles of operation and performance to the predicate and performance testing demonstrates that the proposed device is substantially equivalent to the predicate.