April 30, 2021

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

Re: K203601
Trade/Device Name: Innova Nasal Non-Vented Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: March 30, 2021
Received: March 31, 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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203601

Device Name
Innova™ Nasal Non-Vented Mask

Indications for Use *(Describe)*
The Innova™ Nasal Non-Vented Mask is intended to be used as an accessory to CPAP/bi-level positive pressure systems containing exhalation valves. This product is indicated for use with CPAP/Bi-level systems that have adequate alarms for positive pressure delivery failure. The mask is intended for single patient, multi-use in the home, hospital or institutional environment on adult patients (>30kg/66 lbs.).

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

30-Apr-21

Sponsor:
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Tel - 603-758-6625
Fax - 603-758-6699

Sponsor Contact: Jennifer Kennedy – Director of Regulatory and Quality

Submission Correspondent: Paul Dryden
ProMedic, LLC

Proprietary or Trade Name: Innova™ Nasal Non-Vented 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: Innova™ Nasal Non-Vented mask

Predicate Device: K102317 – Sleepnet iQ Ventilation Nasal mask

Device Description:
The Sleepnet Innova™ Non-Vented Nasal mask is a patient interface for use with positive pressure equipment.

There are 2 labeled versions:
- Single patient, multi-use (home or hospital/institutional) up to 6 months
- Single patient, multi-use up to 7 days (hospital/institutional)

Indications for Use:
The Innova™ Nasal Non-Vented Mask is intended to be used as an accessory to CPAP/bi-level positive pressure systems containing exhalation valves. This product is indicated for use with CPAP/BI-LEVEL systems that have adequate alarms for positive pressure delivery failure. The mask is intended for single patient, multi-use in the home, hospital or institutional environment on adult patients (>30kg/66 lbs.).

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 Innova™ Nasal Non-Vented mask is 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 –

- With the exception of headgear, the mask materials which are in patient contact are identical to the Sleepnet reference device.
- Material Certification provided to support biocompatibility evaluation in accordance with ISO 10993-1:2018 and ISO 18562-1:2017
- The material of the headgear has been tested per ISO 10993-5:2009 and ISO 10993-10:2010

Bench testing

- Pressure drop
- Unintentional leak
- Internal Volume / Dead space
- Mechanical drop test
- Cleaning validation
- Shelf-life via Accelerated aging per ASTM F1980:16
- Testing following ISO 17510:2015

We have demonstrated that the proposed device is equivalent to the predicate, K102317.

Table of Comparison to Predicate

Attributes	Subject Innova nasal non-vented mask	Predicate iQ Ventilation nasal mask	Explanation of Differences
510(k)	K203601	K102317	- -
Product Classification CFR	BZD CFR 868.5905	BZD CFR 868.5905	Similar
Indications for Use	The Innova™ Nasal Non-Vented Mask is intended to be used as an accessory to CPAP/bi-level positive pressure systems containing exhalation valves. This product is indicated for use with CPAP/BI-LEVEL systems that have adequate alarms for positive pressure delivery failure. The mask is intended for single patient, multi-use in the home, hospital or institutional environment on adult patients (>30kg/66 lbs.).	The iQ Ventilation Nasal Mask is to be used as an accessory to CPAP/bi-level positive pressure systems that have adequate alarms for positive pressure delivery failure. Use of this product is indicated for use with CPAP/BI-LEVEL POSITIVE PRESSURE SYSTEMS CONTAINING EXHALATION VALVES. The iQ Ventilation Nasal Mask is intended for single patient multi-use in the home environment and multiple patients multi-use in the hospital/institutional environment.	Similar. • Both devices intended for use with positive pressure devices that have exhalation valves. • Both devices intended for use with devices that have adequate alarms and safety systems in case of failure. • The predicate device was cleared for multi-patient use in the hospital/institutional environment. The subject device will be single patient use only.
Patient Population	Adult (>30 kg)	Adult (>30 kg)	Similar
Patient type	Patients who are appropriate candidates for non-invasive ventilation	Patients who are appropriate candidates for non-invasive ventilation	Similar
Prescriptive	Yes	Yes	Similar
Principle of Operation	Provides a seal over the nose 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 device is passive until connected to the ventilator.	Provides a seal over the nose 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 device is passive until connected to the ventilator.	Similar

Attributes	**Subject** **Innova nasal non-vented mask**	**Predicate** **iQ Ventilation nasal mask**	**Explanation of Differences**
Therapy Pressure Range	4 cm H_2O – 20 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.	Similar This rating is dependent on the equipment to which the device is attached. The subject device has a minimum pressure of 4 cm H_2O. Most new positive pressure devices have a minimum pressure setting of 4 cm H_2O.
Anatomical site	Face (seals around nose)	Face (seals around nose)	Similar
User Interface to administer therapy	Masks have a standard 22mm connection that connects to 22mm ventilator circuits.	Mask incorporates a tapered tubing, which has a standard 22mm connection that connects to 22mm ventilator circuits.	Similar
Contraindications	None	None	Similar
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.	Similar
Use life	**Innova nasal non-vented mask** Home use – Single patient, multi-use up to 6 months **Innova hospital nasal non-vented mask** Single patient, multi-use up to 6 months Disposable, Single patient use up to 7 days	Single patient use – 6 months Multi patient use - 6 months	Similar. • Removed multi-patient use for the subject device. • Added Innova Hospital nasal non-vented mask for short-term single patient use (up to 7 days) and single patient, multi-use for up to 6 months in the hospital/institutional environment.
Shelf life	5 years	No shelf life stated	Similar There is no shelf life for both subject and predicate. 5 year shelf life has been validated for the subject device
Non-sterile	Yes	Yes	Identical

Attributes	Subject Innova nasal non-vented mask	Predicate iQ Ventilation nasal mask	Explanation of Differences
Cleaning methods	**Innova nasal non-vented mask -** • Mild Soap (such as Ivory) and water **Innova hospital nasal non-vented mask -** • Mild Soap (such as Ivory) and water • 70% Isopropyl alcohol	Mild Soap/dish detergent and water	Similar 70% isopropyl alcohol has been added for the short term hospital use mask. This method has been validated. This method is similar to Sleepnet Veraseal 3 full face non-vented mask - K190533.
Features			
Available sizes	2 - Small/Medium & Medium/Large	1	Similar The Medium/Large size is similar to the predicate device. The Small/Medium size is smaller. The dead space of both sizes of the subject device is lower than the predicate device but does not raise new safety concerns.
Shape	Similar	Similar	Similar
Incorporates an Exhaust elbow	No	No	Similar
Components of the mask	• Mask shell • Gel bladder • Non-vented elbow • Headgear	• Mask shell • Gel bladder • Non-vented elbow • Headgear • Tubing	Similar
Shell design	Rigid	Soft	Similar Shell geometry is similar for both devices. Soft shell incorporated in the predicate device for comfort feature, but the functionality is the same. Rigid shell in the subject device uses the same material as the Sleepnet V3 full face vented mask - K190254, which has a similar environment and duration of use.

Attributes	**Subject** **Innova nasal non-vented mask**		**Predicate** **iQ Ventilation nasal mask**		**Explanation of Differences**
Patient Contact per ISO 10993-1	Surface contact with intact skin Externally Communicating with tissue (gas pathway) Permanent contact		Surface contact with intact skin Externally Communicating with tissue (gas pathway) Permanent contact		Similar safety profile
Performance Characteristics					
Dead space (ml)	Small/Medium size – 78 ml Medium/Large size – 100 ml		120 ml		The dead space of both sizes of the subject device is lower than the predicate device.
Resistance to flow (pressure drop) (cm H_2O)	@ 30 lpm – 0.10 cm H_2O @50 lpm – 0.33 cm H_2O @ 60 lpm – 0.46 cm H_2O @100 lpm – 1.42 cm H_2O		@ 30 lpm – 0.31 cm H_2O @ 60 lpm – 1.28 cm H_2O		The subject device has a lower pressure drop compared to the predicate. There are no performance requirements for pressure drop. The pressure drop for a device is disclosed in labeling consistent with the ISO 17510:2015 requirements.
Unintentional leak (lpm)	**Pressure (cm H_2O)** 5 10 15 20 25 30	**Unintentional leak (lpm)** 4.86 9.20 11.43 14.70 17.53 20.33	**Pressure (cm H_2O)** 5 10 15 20 25 30	**Unintentional leak (lpm)** 3.2 5.6 9.0 10.8 12.5 14.3	The subject device has a higher unintentional leak than the predicate. Positive pressure ventilators have leak compensation to account for this unintentional leak. Leak compensation found on these devices is 50 lpm or greater. So long as the unintentional leak of the mask is lower than 50 lpm, this leak does not cause any loss of therapy. The maximum leak is below this threshold.

510(k) Summary

30-Apr-21

Substantial Equivalence Conclusion:

The Innova™ Nasal Non-Vented mask has 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.