K121692

510(k) Summary

NOV 5 2012

SleepNet Corporation
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Hampton, NH 03842

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Official Contact: Jennifer Kennedy – Director of Quality

Proprietary or Trade Name: MiniMe 2 Nasal Mask

Common/Usual Name: Patient interface

Classification Code/Name: BZD – non-continuous ventilator (IPPB)
21CFR 868.5905
Class 2

Device: MiniMe 2 Nasal Mask

Predicate Devices: K090935 – SleepNet MiniMe pediatric nasal mask
K060105 – ResMed Kidsta Pediatric Mask

Device Description:
The MiniMe 2 Nasal mask is intended to provide a patient interface for application of positive pressure therapy. The mask is to be used as an accessory to CPAP or Bi-level positive pressure systems. It is intended for patients >2 years old and <12 years old. The mask is designed and labeled for different durations of use:

- Single use, disposable (hospital or institutional settings)
- Single patient, multi-use (home setting)
- Single patient, short-term use up to 7 days (hospital or institutional settings)

These indications for use are identical to the predicate SleepNet MiniMe Pediatric Nasal mask, K090935.

The durations for use are identical to

- SleepNet MiniMe Pediatric Nasal mask, K090935 for
  - Single patient, multi-use (home)
  - Single patient, multi-use < 7 days is a subset of the single patient, multi-use (hospital / institutional)
- Single patient, disposable (hospital / institutional) is a shorter duration of use and a labeling claim only.
  - The design, materials, and performance are identical to the predicates and would not be considered a new indication that raises new safety or effectiveness concerns.

Indications for Use:
The MiniMe 2 Nasal masks are intended to provide a patient interface for application of positive pressure therapy. The mask is to be used as an accessory to CPAP or Bi-level positive pressure systems. It is intended for patients >2 years old and <12 years old. The mask is designed and labeled for different durations of use:

- Single use, disposable (hospital or institutional settings)
- Single patient, multi-use (home setting)
- Single patient, short-term use up to 7 days (hospital or institutional settings)

Patient Population: Patients >2 years old and <12 years old

Environment of Use: Home or hospital / institutional environments

Predicate Device Comparison:
The MiniMe 2 Nasal masks are viewed as substantially equivalent to the predicate device because:

Indications –

- The MiniMe 2 Nasal masks are intended to provide a patient interface for application of positive pressure therapy. The mask is to be used as an accessory for use with CPAP or Bi-level positive pressure systems intended to provide an interface for application of CPAP or bi-level therapy. Identical to SleepNet MiniMe Pediatric Nasal mask (K090935).
- **Discussion** – The indications for use are identical to the predicate, SleepNet MiniMe Pediatric Nasal mask (K090935).

Patient Population –

- The masks are for patients > 2 yo and < 12 yo for whom positive airway pressure therapy has been prescribed. Identical to SleepNet MiniMe (K090935).
- **Discussion** – The population is identical to the predicate, SleepNet MiniMe Pediatric Nasal mask (K090935).

Technology –

- Identical technology to – SleepNet MiniMe Pediatric Nasal mask – K090935
- **Discussion** – The technology, shape, design, configuration of the mask, head strap as well as the manufacturing methods are identical to the predicate, SleepNet MiniMe Pediatric Nasal mask – K090935.

The use of multiple ports in the elbow for exhalation and CO_2 washout is substantially equivalent as demonstrated by the comparative Pressure vs. Flow curves and the CO_2 washout testing vs. the predicate ResMed Kidsta (K060105).

Materials –

- The materials in patient contact are identical or have been tested per ISO 10993 to our own predicate devices
- **Discussion –** The materials utilized in the MiniMe 2 are commonly used in medical devices and are either identical to the predicate or have been tested per ISO 10993 and found to be acceptable for the intended use.

Environment of Use –

- The masks are intended for use in the home or hospital/institutional environment.
- Identical to predicate SleepNet MiniMe Pediatric Nasal mask (K090935)
- **Discussion** – The environments of use are identical to the predicate.

See Table 1 for comparison.

Non-Clinical Testing Summary:

Comparative Performance -
We have performed comparative performance testing that included:

- Exhaust Flow (Pressure vs. Flow)
- Pressure Drop / Resistance to Flow
- Internal Volume / Dead space
- CO_2 washout per ISO 17510-2
- Cleaning validation
- Environmental testing
- Mechanical testing - Drop Test

Discussion – The comparative performance and specifications demonstrate that the MiniMe 2 is equivalent in performance to the predicates.

Biocompatibility of Materials –
Materials listed in the following table are either identical to predict ate SleepNet mask or were evaluated per ISO 10993-1.

Parts which are Externally communicating, Tissue – gas pathway contact, permanent duration. Pass / fail criteria was for the each respective ISO 10993 test

Parts which are Surface communicating, Skin, permanent duration. Pass / fail criteria was for the each respective ISO 10993 test

Discussion – The listed materials are either identical to predicate SleepNet mask which have the same patient contact and duration of use or were tested per ISO 10993-1.

See Table 2 for a list of materials, patient contact and duration of use.

Table 1 Comparison to Predicates

Attributes	**MiniMe 2 Nasal Mask**	**SleepNet MiniMe Nasal Mask K090935**	**ResMed Kidsta K060105**
Indications for Use	Intended to provide a patient interface for application of positive pressure therapy. The mask is to be used as an accessory to CPAP or Bi-level positive pressure systems.	Intended to provide an interface of CPAP or bi-level therapy to patients.	Intended to provide non-invasive ventilation with RI or OSA
Patient Population	>2 yo to <12 yo	>2 yo to <12 yo	> 7 yo and up
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.	The masks are intended for use in the home or hospital/institutional environment.
Duration of Use	Single patient, disposable (hospital or institutional settings) Single patient, multi-use (home setting) Single patient, short-term use up to 7 days (hospital or institutional settings)	 Single patient, multi-use (home setting) Single patient, short-term use up to 7 days (hospital or institutional settings)	 Single patient, multi-use (home setting)
Prescriptive	Yes	Yes	Yes
Cleaning	Soap and water	Soap and water	Soap and water
Incorporates Exhalation port with multiple holes	Yes	Yes	Yes
Non-vented elbow configuration used with circuit with integrated exhalation valve	Yes	Yes	N/A
Delivered Pressure range	4 – 20 cm H_2O	3 – 20 cm H_2O	>4 cm H_2O

Attributes	**MiniMe 2 Nasal Mask**	**SleepNet MiniMe Nasal Mask K090935**	**ResMed Kidsta K060105**
Features			
Available sizes	2	1	Multiple
Shape	Similar triangular shape	Similar triangular shape	Similar triangular shape
Shell	Hard Soft	Soft	Hard
Materials	Identical to other SleepNet masks or tested per ISO 10993		
CO_2 washout profile Tested per ISO 17510-2 (largest size tested, which is worst case)	**Pressure** **$ETCO_2$% at mask (% increase)** 4 cm H_2O 5.3 (6%) 5 cm H_2O 5.2 (4%) 10 cm H_2O 5.1 (3%) Occluded 5.3 (7%)	This is a small mask so we compared to equivalent size of the Kidsta	**Pressure** **$ETCO_2$% at mask (% increase)** 4 cm H_2O 5.8 (14%) 5 cm H_2O 5.7 (12%) 10 cm H_2O 5.5 (7%) Occluded 6.8 (34%)
Dead space Small Large	25 ml 40 ml	21 ml	81 ml 81 ml
Exhaust – pressure / flow	Pressure (cmH_2O) Flow (lpm) 4 17.1 12 33.5 20 43.6	Pressure (cmH_2O) Flow (lpm) 4 19.1 12 34.8 20 45.8	Pressure (cmH_2O) Flow (lpm) 4 19.5 12 36.2 20 48.7
Resistance to Flow (Flow and pressure)	30 lpm – 0.22 cm H_2O 50 lpm – 0.72 cm H_2O 60 lpm – 1.03 cm H_2O 100 lpm – 3.09 cm H_2O	30 lpm – 0.10 cm H_2O 50 lpm – 0.36 cm H_2O 60 lpm – 0.54 cm H_2O 100 lpm – 1.71 cm H_2O	With 15mm tubing 30 lpm – 0.12 cm H_2O 50 lpm – 0.44 cm H_2O 60 lpm – 0.67 cm H_2O 100 lpm – 2.10 cm H_2O
Components	Headgear Shell / Cushion Swivel elbow Tubing	Headgear Shell / Cushion Swivel elbow Tubing	Headgear Shell / Cushion Swivel elbow Tubing

Table 2

Materials in the Patient Contact

Component	Patient Contact / Duration (all are permanent)	Biocompatibility
Gel Bladder	Skin and Gas Pathway	Identical Sleepnet MiniMe Pediatric mask K090935
Bladder film	Skin and Gas Pathway	Identical Sleepnet MiniMe Pediatric mask K090935
Shell	Gas Pathway	Identical Sleepnet IQ Ventilation mask K102317 Sleepnet MiniMe Pediatric mask K090935
Elbow assembly	Gas Pathway	Identical Sleepnet MiniMe Pediatric mask K090935
Headgear	Skin	Identical Sleepnet IQ Ventilation mask K102317
Tubing	Gas Pathway	Cytotoxicity Sensitization Genotoxicity Implantation Intracutaneous Systemic Toxicity
Swivel Connector	Gas Pathway	Identical Sleepnet IQ Nasal mask K993269
Tubing Connector	Gas Pathway	Identical Sleepnet IQ Nasal mask K993269
15 mm Connector	Gas Pathway	Identical Sleepnet IQ Nasal mask K021534

Substantial Equivalence Conclusion -

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 5, 2012

SleepNet Corporation
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

Re: K121692
Trade/Device Name: MiniMe 2 Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: September 18, 2012
Received: September 19, 2012

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer Digitally signed by Kwame O. Ulmer DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Kwame O. Ulmer, 0.9.2342.19200300.100.1.1=1300183618 Date: 2012.11.05 14:42:55 -05'00' for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K121692

Device Name: MiniMe 2 Nasal Mask

Indications for Use:

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Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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