K121321

510(k) Summary
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19-Nov-12

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Official Contact: Jennifer Kennedy – Director of Quality

Proprietary or Trade Name: Innova Nasal Vented Mask

Common/Usual Name: Patient interface

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

Predicate Device: K092835 - Respironics ComfortGel Blue nasal mask

Device Description:
The SleepNet Innova Nasal Vented Mask is similar to other CPAP mask. The Innova Nasal Vented mask is nearly identical to our iQ Nasal mask, K102317, except for the following changes:

- Slightly different indications for use, but the predicate is Respironics ComfortGel Blue Nasal mask, K092835.
- A range of durations of use for marketing purposes only
  - single use, disposable
  - single patient, multi-use up to 7 days
  - single patient, multi-use in home setting
  - multi-patent, multi-use in institutional settings
- material for shell, hard vs. soft
- a new exhaust elbow design

Indications for Use:
The Innova Nasal Vented Mask is intended to provide an interface for application of positive airway pressure therapy, such as CPAP or bi-level.

- The mask is intended for:
- Single use, disposable
- Single patient, multi-use in the home setting
- Multi-patient, multi- use in the hospital or institutional settings
- Single patient, short-term use (up to 7 days) in the hospital or institutional settings

The masks are to be used on adult patients (>66 lbs. / >30 kg) for whom CPAP or bi-level therapy has been prescribed.

Patient Population: For adults (> 66 lbs. / >30 kg)

Environment of Use: Home or hospital or institutional environments

Predicate Device Comparison:
The Innova Nasal Vented Mask as compared to the predicate is viewed as substantially equivalent to the predicate device because:

Indications –

- The Innova Nasal Vented Mask is intended to provide a patient interface for application of positive airway pressure therapy with CPAP or bi-level devices.

  The masks are to be used on adult patients (>66lbs. / >30 kg) for whom positive airway pressure therapy has been prescribed. Identical to Respironics ComfortGel Blue Nasal (K092835)

Discussion – The indications for use are identical to the predicate Respironics ComfortGel Blue Nasal (K092835)

Patient Population –

- The masks are to be used on adult patients (>66 lbs. / >30 kg) for whom positive airway pressure therapy has been prescribed. Identical to Respironics ComfortGel Blue Nasal (K092835)

Discussion – The patient population is identical to the predicate Respironics ComfortGel Blue Nasal (K092835).

Technology –

- Technology, method of manufacture and construction of a gel cushion, hard or soft shell and elbow with exhalation holes are identical to the predicate SleepNet iQ Nasal mask – K102317 and similar to the predicate Respironics ComfortGel Blue Nasal (K092835).

Discussion – The technology, shape, design, configuration of the mask, head strap as well as the manufacturing methods are identical to the predicate, SleepNet iQ Nasal mask (K102317).

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 Respironics ComfortGel Blue Nasal (K092835) and the differences are not clinically significant and do not affect safety and effectiveness.

Environment of Use –

- The masks are intended for use in the home or hospital or institutional environment. Identical to predicate – Respironics ComfortGel Blue Nasal (K092835)

Discussion – The environments of use are identical to the predicate.

Environment of Use –

- The masks are intended for use in the home or hospital or institutional environment. Identical to predicate – Respironics ComfortGel Blue Nasal (K092835)

Discussion – The environments of use are identical to the predicate.

Table of Comparison to Predicate

Attributes	**Innova Nasal vented mask**	**Respironics ComfortGel Blue K092835**
Indications for Use	The Innova Nasal Vented Mask is intended to provide an interface for application of positive airway pressure therapy, such as CPAP or bi-level. The mask is intended for: • Single use, disposable • Single patient, multi-use in the home setting • Multi-patient, multi- use in the hospital or institutional settings • Single patient, short-term use (up to 7 days) in the hospital or institutional settings The masks are to be used on adult patients (>66 lbs. / >30 kg) for whom CPAP or bi-level therapy has been prescribed.	The ComfortGel Blue Nasal Mask is intended to provide an interface of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital / institutional environment. The mask is to be used on adult patients (>66 lbs. / >30 kg) for whom CPAP or bi-level therapy has been prescribed.
Patient Population	Adult (>66 lbs. / >30 kg)	Adult (>66 lbs. / >30 kg)
Environment of Use	The masks are intended for use in the home or hospital or institutional environment.	The masks are intended for use in the home or hospital/institutional environment.
Prescriptive	Yes	Yes
Duration of Use	Single use, disposable Single patient, multi-use Multi-patient, multi- use Single patient, short-term use (up to 7 days)	 Single patient, multi-use Multi-patient, multi-use
Cleaning methods	Soap and water OPA	Soap and water
Incorporates an Exhaust port elbow	Yes	Yes
Delivered Pressure range	4 – 20 cm H_2O	4 – 30 cm H_2O
Available sizes	3	4
Shape	Similar	Similar
Shell	Rigid	Rigid
Materials	Identical to Minime K090935 or iQ Nasal K102317	

Attributes	**Innova Nasal vented mask**	**Respironics ComfortGel Blue K092835**
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 6.0 (15%) 5 cm H_2O 5.9 (14%) 10 cm H_2O 5.8 (11%) Occluded 6.7 (30%)	Pressure / $ETCO_2$% at mask (% increase) 4 cm H_2O 5.6 (6%) 5 cm H_2O 5.5 (3%) 10 cm H_2O 5.4 (2%) Occluded 6.3 (19%)
Deadspace Small Medium Large	 82 ml 100 ml 108 ml	 97 ml 99 ml 118 ml
Exhaust – pressure / flow	Pressure (cmH_2O) / Flow (lpm) 4 18.2 10 30.4 20 43.8	Pressure (cmH_2O) / Flow (lpm) 4 17.3 10 27.0 20 38.7
Pressure Drop	30 lpm - 0.04 cm H_2O 50 lpm – 0.16 cm H_2O 60 lpm - 0.24 cm H_2O 100 lpm – 0.82 cm H_2O	30 lpm - 0.04 cm H_2O 50 lpm – 0.15 cm H_2O 60 lpm - 0.22 cm H_2O 100 lpm – 0.74 cm H_2O
Components	Headgear Shell / Cushion Swivel elbow	Headgear Shell / Cushion Swivel elbow

Non-clinical Testing Summary

Comparative Performance -

We have performed comparative performance testing pre- and post-conditioning that included:

Exhaust Flow (Pressure vs. Flow)

- Standard test method using CPAP unit at various flow rates and measuring the leak at the patient interface
- No pass / fail criteria, reportable values only. It should be comparable to the predicate.
- Discussion – The proposed device has equivalent "Leak or Flow" rate at all pressure vs. the predicate. The differences do not have any clinical significance

Pressure Drop (resistance to Flow)

- Standard test method of using a standard flow and measuring pressure drop
- No pass / fail criteria, reportable values only
- Discussion – The proposed device is equivalent to the predicate.

Internal Volume / Deadspace

- Standard test method of measuring the volume of the parts near the patient.
- No pass / fail criteria, reportable values only. It should be comparable to the predicate.
- Discussion – The proposed device is equivalent and CO_2 washout and Pressure vs. Flow are the key performance features for CPAP mask performance. The difference4s are not clinically significant and do not raise any new safety or effectiveness concerns.

CO_2 washout

- Tested per ISO 17510-2
- Pass / fail criteria per ISO 17510-2 allow for changes in CO_2 at various pressures to be < 20% and < 60% from baseline).
- Discussion - the performance of the proposed device is well within the pass / fail criteria as stated in ISO 17510-2.

Cleaning validation

- Repeated cleaning was performed per the recommended cleaning instructions
- Visual and performance testing was performed and compared pre – and post- cleaning and found to be similar
- Discussion – The proposed mask can be cleaned as intended and meet its performance specifications

Environmental / Mechanical testing

- Test method included subjecting samples to high and low temperatures and a drop test
- Pass / fail criteria was that they would meet the performance specifications which was performed after the cleaning durability
- Discussion – The proposed device met the performance specifications after conditioning and cleaning.

Materials –

- The materials in patient contact are identical to our own predicate devices SleepNet iQ Nasal (K102317) and MiniMe mask (K090935).
- Discussion – The materials are identical to the cited predicates.

Materials / Patient Contact / Duration of Use (prolonged duration of use)

Component	Patient Contact	Predicate for Biocompatibility
Gel Bladder	Surface contact Skin External communicating, Tissue / Gas Pathway	Identical - Sleepnet MiniMe Pediatric mask K090935
Bladder film	Surface contact Skin External communicating, Tissue / Gas Pathway	Identical - Sleepnet IQ Ventilation mask K102317
Shell	External communicating, Tissue / Gas Pathway	Identical - Sleepnet MiniMe Pediatric mask K090935
Elbow assembly	External communicating, Tissue / Gas Pathway	Identical - Sleepnet MiniMe Pediatric mask K090935
Headgear	Surface contact Skin	Identical - Sleepnet IQ Ventilation mask K102317

Substantial Equivalence Conclusion -

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate can be found to be 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 30, 2012

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

Re: K121321
Trade/Device Name: Hard Shell Vented Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: November 19, 2012
Received: November 20, 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

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

Enclosure

Indications for Use Statement

510(k) Number: K121321 (To be assigned)

Device Name: Hard Shell Vented Nasal Mask

Indications for Use:

The Hard Shell Vented Nasal Mask is intended to provide an interface for application of positive airway pressure therapy, such as CPAP or bi-level.

The mask is intended for:

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

The masks are to be used on adult patients (>66 lbs. / >30 kg) for whom CPAP or bi-level therapy has been prescribed.

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)

Lester W. Schultheis Jr
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K121321