K120463

JUL 27 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: Mojo Full Face Mask
Veraseal Full Face mask

Common/Usual Name: Patient interface

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

Device: Mojo Full Face Mask
Veraseal Full Face mask

Predicate Devices: K060273 – SleepNet Mojo Full Face mask
K063122 – ResMed Mirage Quattro Full Face mask

Device Description:
The SleepNet Mojo and Veraseal Full Face mask are modifications of the SleepNet Mojo Full Face mask cleared under K060273.

The modifications to the cleared Mojo Full Face mask are:

- different durations of use
  - single use, disposable (Hospital/Institutional) - Veraseal
  - single patient, multi-use up to 7 days (Hospital/Institutional) - Veraseal
  - single patient, multi-use (Home or Hospital/Institutional) - MoJo
- a change in materials
- updated design of the exhaust elbow used with the mask

As a result of these modifications we have established two (2) product tradenames to help distinguish them.

Veraseal model has 2 durations of use - single use, disposable or single patient, multi-use up to 7 days in the hospital.

Mojo model is single patient, multi-use (typically more than 7 days) for use in the home or hospital.

Indications for Use:
The SleepNet Mojo and Veraseal masks are intended to be used with positive airway pressure devices, such as CPAP or bi-level, operating at or above 3 cm H2O.

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

Veraseal –

Disposable single use (hospital/institutional)
Single patient, multi-use up to 7 days (hospital/institutional)

Mojo –

Single patient, multi-use (home or hospital/institutional)

Patient Population: For adults (>30 kg)

Environment of Use: Home or hospital / institutional environments

The SleepNet Veraseal and Mojo Full face mask are viewed as substantially equivalent to the predicates device because:

Indications –

- The Veraseal and Mojo masks are intended to be used with positive airway pressure devices, such as CPAP or bi-level operating at or above 3 cm H_2O.

  The masks are to be used on adult patients (>30kg) for whom positive airway pressure therapy has been prescribed.
- Identical to ResMed Mirage Quattro (K063122) with pressure minimum identical to SleepNet Mojo (K060273)

Patient Population –

- The masks are to be used on adult patients (>30kg) for whom positive airway pressure therapy has been prescribed.
- Identical to SleepNet MoJo (K060273) and ResMed Mirage Quattro (K063122)

Technology –

- Identical technology to – SleepNet Mojo Full Face mask (K060273)

Materials –

- The materials in patient contact are identical to predicate devices or have been tested in accordance with ISO 10993.

Environment of Use –

- The masks are intended for use in the home or hospital/institutional environment
- Identical to predicates – SleepNet MoJo (K060273) and ResMed Mirage Quattro (K063122)

Duration of Use and Cleaning Method

- The duration of use and cleaning methods for single patient Less 7 days, single patient, multi-use, disposable are identical to the predicate - SleepNet MoJo (K060273)

Differences –

- There are no differences between the predicates and the proposed modified devices which would raise any new safety or risks and thus can be found to be substantially equivalent.

Comparative Performance

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

- Dead space
- Exhaust Flow
- Pressure drop
- Anti-asphyxia valve (AAV) pressure testing
- Exhaust Elbow Change Performance
- CO_2 washout per ISO 17510-2
- ISO 10993 for biocompatibility
- Cleaning validation
- Storage and aging

The results demonstrated that the devices are substantially equivalent.

Table of Comparison to Predicates

Attributes	Modified Mojo and Veraseal Full Face Mask	Mojo Full Face Mask K060273	ResMed Mirage Quattro K063122
Indications for Use	The Veraseal and Mojo masks are intended to be used with positive airway pressure devices, such as CPAP or bi-level, operating at or above 3 cm H_2O. The masks are to be used on adult patients (>30kg) for whom positive airway pressure therapy has been prescribed.	The SleepNet Mojo Full Face 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 for the treatment of adult obstructive sleep apnea. The mask is to be used on adult patients (>30kg) for whom positive airway pressure therapy has been prescribed.	The Mirage Quattro channels airflow noninvasively to a patient from a positive airway pressure device such as continuous positive airway pressure (CPAP) or bi-level system. The Mirage Quattro is to be used by adult patients (> 66 lbs. / > 30 Kg) for whom positive airway pressure has been prescribed.
Patient Population	Adult (>30 kg)	Adult (>30 kg)	Adult (>30 kg)
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.
Prescriptive	Yes	Yes	Yes
Duration of Use	Veraseal Disposable, single patient use (hospital) Single patient, multi-use up to 7 days (hospital) Mojo Single patient, multi-use (home / hospital)	Single patient, multi-use (home or hospital) Single patient, multi-use (home or hospital)	Single patient, multi-use but does not limit the length of re-use (home / hospital)
Cleaning methods	Soap and water Isopropyl alcohol	Soap and water Isopropyl alcohol	OPA
Incorporates an Exhaust elbow	Yes	Yes	Yes

Attributes	**Modified Mojo and Veraseal Full Face Mask**	**Mojo Full Face Mask K060273**	**ResMed Mirage Quattro K063122**
Features			
Available sizes	3	3	4
Shape	Similar	Similar	Similar
Shell	Veraseal Rigid for single patient models Mojo Soft	 Soft only	Similar
Materials ISO 10993	Yes	Yes	N/A
CO_2 washout profile Tested per ISO 17510-2	**Pressure** **$ETCO_2$% at mask (% increase)** 3 cm H_2O 6.1 (17%) 5 cm H_2O 5.9 (14%) 10 cm H_2O 5.8 (12%) Occluded 6.3 (21%)	**Pressure** **$ETCO_2$% at mask (% increase)** 3 cm H_2O 5.9 (15%) 5 cm H_2O 5.8 (14%) 10 cm H_2O 5.6 (9%) Occluded 6.0 (17%)	Not tested as this predicate for duration of use, environment of use, and cleaning method only
Deadspace Small Medium Large	Mojo Veraseal 160 ml 138 ml 185 ml 165 ml 205 ml 181 ml	 200 ml 245 ml 295 ml	Varies according to cushion size 242 ml
Exhaust – pressure / flow	Mojo Pressure (cmH_2O) Flow (lpm) 3 21.20 10 37.20 20 53.10 Veraseal Pressure (cmH_2O) Flow (lpm) 3 21.10 10 36.40 20 53.00	 Pressure (cmH_2O) Flow (lpm) 3 32.00 10 43.00 20 55.00	 Pressure (cmH_2O) Flow (lpm) 4 22 8 32 12 41 20 54

Attributes	**Modified Mojo and Veraseal Full Face Mask**	**Mojo Full Face Mask K060273**	**ResMed Mirage Quattro K063122**
Pressure AAV Opening / closing	Mojo Opening – 1.10 cm H_2O Closing – 1.60 cm H_2O Veraseal Opening – 1.29 cm H_2O Closing – 1.45 cm H_2O Pass / Fail criteria is < 3 cm H_2O	Opening – 0.65 cm H_2O Closing – 1.38 cm H_2O Pass / Fail criteria is < 3 cm H_2O	Not disclosed
Resistance to Flow	Mojo 50 lpm – 0.40 cm H_2O 100 lpm – 0.65 cm H_2O Veraseal 50 lpm – 0.49 cm H_2O 100 lpm – 0.89 cm H_2O	50 lpm – 0.38 cm H_2O 100 lpm – 0.80 cm H_2O	50 lpm – 0.5 cm H_2O 100 lpm – 1.6 cm H_2O
Components	Headgear Shell / Cushion Swivel elbow	Headgear Shell / Cushion Swivel elbow	Headgear Shell / Cushion Swivel elbow

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 27 2012

Sleepnet Corporation
C/O Mr. Paul Dryden
President
Promedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134-2958

Re: K120463
Trade/Device Name: Veraseal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: July 6, 2012
Received: July 9, 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,

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: K120463

Device Name: Mojo Mask
Veraseal Mask

Indications for Use:

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Veraseal –
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Mojo –
- Single patient, multi-use (home or hospital/institutional)

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)

L Schulteis

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

510(k) Number: K120463