K090935

510(k) Summary
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18-Jun-09

JUL - 1 2009

SleepNet Corporation
5 Merrill Industrial Drive
Hampton, NH 03842

Tel - 603-758-6625
Fax - 603-758-6699

Official Contact: Jennifer Kennedy – Director of Quality

Proprietary or Trade Name: MiniMe™ Pediatric Mask

Common/Usual Name: Patient interface

Classification Code/Name: BZD – accessory for ventilator, non-continuous (respirator)
CFR 868.5905

Device: MiniMe™ Pediatric Mask

Predicate Devices: K073600 / K954207 – Respironics ComfortGel
K053352 – Respironics ComfortLite2
K032922 – Airway Development Clarissa
K060105 – ResMed Kidsta
K013306 – SleepNet MiniMe

Device Description:
The SleepNet MiniMe™ Pediatric Mask with vent holes for a fixed leak during use and without vent holes when used with a patient circuit that incorporates its own anti-asphyxia valve.

It is single patient, multi-use or multi-patient, reusable.

Indications for Use:
The MiniMe™ Pediatric Mask is intended to provide an interface for application of CPAP or bi-level therapy. It is intended for patients > 2 years old and < 12 years old. The MiniMe Pediatric Mask is intended for single patient, multi-use in the home environment and multiple patients, multi-use in the hospital/ institutional environment.

Patient Population: For patients aged > 2 years and < 12 years old

Environment of Use: Home or hospital / institutional environments.

The MiniMe™ is viewed as substantially equivalent to the predicate devices because:

Indications –
- Identical to predicates – K954207, K053352

Patient Population –
- Similar to K032922 and K060105 – fits between these populations with no new risks

Technology –

- Identical technology to – SleepNet MiniMe™ - K013306

Materials –

- The materials in patient contact identical to predicate devices

Environment of Use –

- Identical to predicates – SleepNet – K013306, Respironics – K954207 and K053352

Differences –

There are no differences between the predicates and the proposed device. We are only changing the indications for use.

Comparative Performance

We have performed comparative performance testing including – Pressure vs. Flow / leak and Internal volume / dead space testing.

The results demonstrated that the devices were substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 2009

ProMedicm, Incorporated
C/O Paul E. Dryden
President
SleepNet Corporation
24301 Woodsage Drive
Bonita Springs, Florida 34134-2958

Re: K090935
Trade/Device Name: MiniMe™ Pediatric Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: June 18, 2009
Received: June 19, 2009

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.

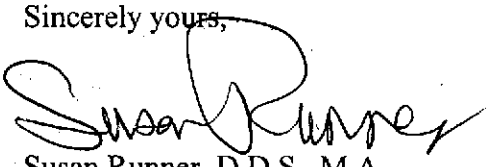
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Susan Runner, D.D.S., M.A.
Acting 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: K090935

Device Name: MiniMe™ Pediatric Mask

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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)

Susan Runyon

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

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