MAY 2

510(k) Summary of Safety and Effectiveness K060273

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter Name:	Sleepnet Corp.
Submitter Address :	1050 Perimeter Rd. Manchester, NH 03103
Contact Person:	Paul Chiesa
Phone Number:	(603) 624-1911
Fax Number:	(603) 641-9440
Date Prepared:	January, 2006
Device Trade Name:	Sleepnet MoJo™
Device Common Name:	Nasal Mask
Classification Name:	Ventilator, Noncontinuous (Respirator), 73BZD
Predicate devices:	TMS Full Advantage™, K043382
Reason for submission:	This device has not been previously marketed in the USA.

Device Description:

The Sleepnet MoJo™ Full Face Mask is an externally placed mask covering the nose and mouth of the patient. It provides a seal such that positive pressure from a positive pressure source is directed to the patient's nose and mouth when either or both are open. It is held in place with an adjustable headgear. It may be cleaned with mild detergent, such as Ivory® dishwasher liquid, in water. The cleaning process requires limited disassembly.

The mask consists of a molded flexible polyvinylchloride shell with a soft, resilient polyurethane encased silicone gel skin-contacting seal that conforms to the patient's facial features. The polyvinylchloride shell contains a malleable metal insert that allows the user to adjust the entire perimeter of the facial seal in any configuration.

The mask connects to a conventional air delivery hose between the mask and the positive airway pressure source via a standard 22 mm polycarbonate elbow/swivel/valve assembly. The elbow/swivel/valve assembly attaches to the front of the mask with a polycarbonate split "c" clip.

The air delivery system consists of a 22mm polycarbonate swivel connector for 22mm tubing. The built in vent ports are located on the elbow/swivel/valve assembly to provide a continuous air leak to prevent rebreathing of deadspace CO2, direct air away from the patient's face and chest, and eliminate the need for a separate exhalation device. The vent ports also allow the patient to exhale normally and do not interfere with the other performance requirements of the device. The vent ports may be visually checked for obstruction prior to use. The elbow/swivel/valve assembly also includes a built in Anti-Asphyxia Valve which allows the patient to continue to breathe fresh air in the event of positive air pressure device failure or output deterioration, or delivery hose kinking/obstruction.

An optional polypropylene adapter sold separately as an accessory may be used to connect to a pressure measurement or oxygen delivering device.

The Sleepnet MoJo™ Full Face Mask assembly will be packaged along with an instructions for use sheet in a standard poly bag.

The Sleepnet MoJo™ headgear is available in a variety of sizes to fit a broad range of facial structures, and attaches to the mask via slots contained within the shell.

Intended Use:

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 intended for single patient use and reuse in the home or hospital/institutional environment. The mask is to be used on adult patients (>30kg) for whom positive airway pressure therapy has been prescribed.

Substantial Equivalence/ Device Technological Characteristics and Comparison to Predicate Device(s):

The technological characteristics of the Sleepnet MoJo™ Full Face Mask are equivalent to the predicate device listed above.

Tests performed on the Sleepnet MoJo™ Full Face Mask demonstrate substantial equivalence to the predicate device listed above.

Conclusion:

The Sleepnet MoJo™ Full Face Mask is substantially equivalent to the predicate device in terms of safety, effectiveness, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Paul Chiesa
President
Sleepnet Corporation
1050 Perimeter Road
Manchester, New Hampshire 03103

MAY 2 2006

Re: K060273
Trade/Device Name: Sleepnet MoJo™ Full Face Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: January 31, 2006
Received: February 2, 2006

Dear Mr. Chiesa:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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

510(k) Number: K060273

Device Name: Sleepnet MoJo™ Full Face Mask

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

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...ol. Dental Devices
K060273