K112822

DEC 2 7 2011

510(K) SUMMARY

S.L.P Ltd

SleepStreep II

7.1.1 Applicant's Name:

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7.1.2 Contact Person:

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7.1.3 Date Prepared: September 2011

7.1.4 Trade Name: SleepStreep II

7.1.5 Classification Name: Ventilatory effort recorder (Breathing frequency monitor)

7.1.6 Classification: Class II; Product Code MNR;
Regulation No. 868.2375
Panel: Anesthesiology

7.1.7 Predicate Device: SleepStip cleared under K002135.

7.1.8 Device Description: The SleepStrip II is formed like a soft plastic "strip" or patch which is adhesively applied on the face under the nose for one night sleep. The SleepStrip II device comprises the following four main components:

1. Flexible body.
2. Sensor and signal acquisition and analysis hardware and firmware.
3. Battery as a power source.
4. A result display element.

The SleepStrip II is designed to show a Sleep Apnea Syndrome (SAS) study results. It includes sensors, hardware and software to facilitate a sleep apnea screening study at the patient's home over one night sleep (under prescription). The SleepStrip II, detects and counts respiratory events (apneas and hypopneas) in real time.

7.1.9 Intended Use:

The SleepStrip II is intended to measure apnea/hyponea events during sleep for the purpose of prescreening patients for sleep apnea syndrome. The device is intended to be used by adult patients as prescribed by a physician in either home, hospitalor facility use settings.

7.1.11 Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, the SleepStrip II complies with the voluntary standards such as IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4 and AAMI / ISO 14971-1.

7.1.12 Performance Data & Substantial Equivalence

The SleepStrip II is substantially equivalent in all aspects, e.g., technological characteristics, mode of operation, performance characteristics, intended use, etc., to the commercially available SleepStrip, previously cleared under K002135.
The difference between the modified and the cleared SleepStrip devices is that the new model incorporates:

- Addition of a pressure/flow sensor
- Change of display from electrochemical Apnea/hypopnea count display to LED based three level severity display.
- Change of mechanical construction from plastic film to elastic case.
- Use of a single thermal sensor instead of using three sensors located in the airflow.
- Activation/readout by pushing a button, instead of placing/removing gel patch.

A series of performance testing, including bench testing, software validation and laboratory safety and EMC testing were performed to demonstrate that the modified SleepStrip II does not raise any new questions of safety and efficacy. These tests include:

- Software verification and validation
- Bench tests /Performance testing: Pressure Channel signal validity;
- Bench tests /Performance testing: Thermal Channel signal validity; and
- Bench tests /Performance testing: Final Scoring Validity

Based on these tests results, S.L.P Ltd. believes that the modified SleepStrip II is substantially equivalent to the cleared SleepStrip without raising new safety and/or effectiveness issues.

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

Mr. Noam Hadas
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DEC 2 7 2011

Re: K112822
Trade/Device Name: SleepStrip II
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: September 22, 2011
Received: September 28, 2011

Dear Mr. Hadas:

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 (if known):_____

Device Name: SleepStrip II

Indications for Use:

The SleepStrip II is intended to measure apnea/hyponea events during sleep for the purpose of prescreening patients for sleep apnea syndrome. The device is intended to be used by adult patients as prescribed by a physician in either home, hospital or facility use settings.

Prescription Use __√__ (Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use____ (Part 21 C.F.R. 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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