OCT 6 - 2004

510(K) SUMMARY

SleepSense Sleep Sensors

510(k) Number K 042253

Applicant's Name: S.L.P Ltd.

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Contact Person: Noam Hadas

S.L.P Ltd.

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Trade Name:

SleepSense sleep disorder sensors

Classification Name:

MNR - Ventilatory effort recorder

Classification:

The FDA has classified sensors for sleep disorder sensor device as class II devices. EPM development systems have classified the predicate devices as product code BZQ (monitor, respiration frequency). SLP selected to classify these products as product code MNR (Respiration effort recorder) under the same regulation #. 868.2375. This classification is based on the fact that these products do not monitor, but only output signals which are recorded in a system.

No monitoring takes place at all, since no indication of the patient's condition is presented to any caregiver, there is no need or intention to treat the patient, and there are no alarms or thresholds of any kind.

Predicate Device:

Device	Applicant	510(k)	Decision Date
snoring sensor	EPM development systems	K941759	11/10/1994
moving images(tm)	EPM information systems	K935518	05/17/1994
the tracker	EPM information systems	K923033	06/01/1993
easyflow	EPM information systems	K922112	12/07/1992
resp-ez(tm) respirat	EPM information systems	K903300	12/28/1990

Performance Standards:

No performance standards are specified for physiological sensors for sleep disorder testing. The SleepSense sensors are designed, and are specified to be used, only with FDA approved sleep recording systems, which are required to comply with all electrical safety requirements as specified in IEC 60601-1.

Intended Use:

SleepSense sensors provide a qualitative measure of a patient's physiological parameters for recording onto an FDA-cleared data acquisition system. Their target population: Children and adult patients who are screened during sleep disorder studies. Their environment of use is usually at a sleep laboratory or sometimes at the patient's home.

Device Description:

Monitoring various physiological parameters is standard practice in sleep disorder testing. Standard overnight recordings show, among others, traces of parameters like respiration movement, leg and arm movement, snoring sounds, respiration airflow and body position during sleep.

In order to record tracings showing these parameters, sensors are needed to convert the physiological parameter into an electrical signal. These sensors are very simple sensing

elements like piezo-crystals that convert mechanical force or vibrations to an electrical signal. Other sensing elements may be thermocouples which generate a signal proportional to temperature, or gravity switches, that switch and electrical circuit on and off depending on their position.

In practice, these sensing elements are packaged in small, patient-friendly enclosures which are applied to the patient, and connected to the recording system via a long and flexible cable. There is no electrical contact of any kind between the sensors and the patient.

All signals received from the sensors are qualitative, and are only used to record the dynamic nature or existence of the physiological parameter recorded. A specially trained sleep technician called "scorer" reviews the overall recording in the morning following the study. The signals recorded, together with additional channels like EKG or EEG, are analyzed to arrive at a diagnosis of a sleep disorder like sleep apnea or insomnia.

Substantial Equivalence:

S.L.P Ltd. claims that SleepSense sensors are the same products as the predicate devices, since S.L.P is the designer and OEM manufacturer of the sensors distributed by EPM since 1990. It is therefore obvious that they are substantially equivalent to these predicate devices cited above, without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 - 2004

S.L.P. Limited
C/O Ms. Patricia Murphy
Responsible Third Party Official
KEMA Quality BV
4377 County Line Road
Chalfont, Pennsylvania 18914

Re: K042253
Trade/Device Name: SleepSense Sleep Sensors
Regulation Number: 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: October 4, 2004
Received: October 4, 2004

Dear Ms. Murphy:

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.

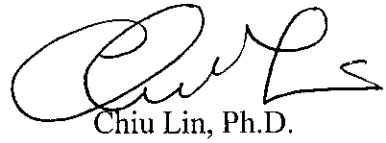
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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/dsma/dsmamain.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 STATEMENT

510(k) Number: _____

Device Name: SleepSense sensors for sleep disorder testing

Indications for Use:

SleepSense sleep sensors provide a qualitative measure of some physiological parameters for recording onto an FDA-cleared data acquisition system. Their target population: Children and adult patients who are screened during sleep disorder studies. Their environment of use is usually at a sleep laboratory or sometimes at the patient's home.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K042253

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Number _____

Prescription Use X OR Over the Counter Use_____

(Per 21 CFR 801.109)