K080375

SECTION 5 - 510 (K) SUMMARY

5.1 510(K) SUMMARY

A 510(k) Summary is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990. This 510(k) Summary meets the requirements identified in 21 C.R.F. 807.92.

RMX Physiological Data Recorder

Date of Preparation	Aug 26, 2008
Applicant's Name	S.L.P Ltd. 62 Anilevitch Street Tel-Aviv 67060, Israel Tel: 972-3-537-1281 Fax: 972-3-537-1282
Establishment Reg. number	9614500
Contact Person	N. Hadas, CTO (see footer for contact details)
Trade Name	RMX
Common Name	Physiological Data Recorder
Classification Name	Ventilatory Effort Recorder
Classification Reg. number	21 CFR 868.2375
Regulatory Status	Class II
Product Code	MNR
Classification panel	Anesthesiology

5.2 DEVICE DESCRIPTION

The RMX is an ambulatory unattended recording device intended for the recording of sleep physiological data. The RMX functions exclusively as a data-recording device and is not intended to monitor Apnea or other vital signs in an intensive care unit or any other real time application. It is used by or on the order of a physician.

The RMX data recording device offers a platform for collecting multiple channels of physiological signals such as pulse rate, ECG, EEG, airflow, thoracic and abdominal respiratory effort, sounds intensity (i.e. noise due to snoring), body position and movements, leg movement, pulse oximetry or similar physiological signals. The data collection box is normally attached over the clothes of the patient's chest using the chest inductive effort sensor band made of clothing-standard woven elastic laces. The device may use its internal sensors, standard wired physiological sensors or several wireless sensors (not covered in this application) to match the specific needs of the patient.

Data collected is transferred on an SD memory card from the recorder to a PC at the physician's clinic, where it is converted into industry standard EDF format, after which it is analyzed by standard scoring software to generate a detailed final report with recommendations.

The RMX data recording device includes 3 software elements; 1) the **SETUP** part that runs on a PC and uploads the recorder setup parameters to the SD (secure digital) card as determined by the physician, 2) The **Firmware** operating the main and auxiliary CPU hardware which control the A/D conversion and storage of the data, and 3) the **Post-Study Software** which runs on a PC, reads the raw data file from the SD card as a single file and converts it into the industry standard EDF format suitable for input to analytical systems (see section 16 for software description).

5.3 INTENDED USE

The RMX is a physiological data recorder intended to collect and record data from multiple physiological channels and additional auxiliary inputs from undesignated channels. It is indicated for use by or on order of a physician. The RMX is intended for use in a supervised (hospital) or unsupervised (home) environment.

5.4 SUBSTANTIAL EQUIVALENCE

S.L.P Ltd. believes that the RMX is substantially equivalent to the following predicate devices without raising any new safety and/or effectiveness issues:

1. Portable sleep data recorder, Pro-tech services Inc., WA, USA, cleared under K033402.
2. DeVilbiss Sleep Recorder,DeVilbiss, PA USA, cleared under K012437.
3. SleepSense Sleep Sensors, S.L.P. LTD., IL, K042253
4. SPO, Pulse Oximeter, SPO LTD., IL, K040178

Detailed description of the predicate devices is provided in **Section 12** of this application.

5.5 TECHNOLOGICAL PROPERTIES

The RMX is a basic physiological signal recorder. Similar to the predicate devices, the RMX uses a set of standard internal and/or external physiological sensors to collect and record multiple physiological parameters such as respiration, movement or sound. All signals are channeled to the main unit recorder which contains a digitizer and a processor to store them on a solid-state memory card.

The predicate devices are identical to the RMX in that they contain similar functional modules, which perform the same functions.

The sensors integrated in the RMX device, or connected externally to the system are based on sensor technology developed by SLP over the last 15 years of making standard sleep lab sensors, and are covered by 510K K042253. The SPO ltd. oximeter used in the system is covered by 510K K040178. Additional sensors or devices such as the pressure cannula are covered by their respective FDA 510K approvals.

Therefore, in design and functionality aspects, the RMX does not raise any new questions of safety or effectiveness. Any minor differences in the design and operational method (intended to help the user perform the recording successfully) between the RMX and its predicate devices do not raise any safety or effectiveness issues.

5.6 FUNCTIONAL TEST

The technical specifications of the RMX were selected to match accepted non-formal standards in the industry, including sampling rates, sampling depths (# of bits per sample), sensor types and attachment location, as well as methods and overall operation protocol. Due to the sole function as a data recorder, validation encompassed a single setup in which the complete RMX device (software and hardware) was tested for its ability to generate, from known simulated signals injected to its inputs, an accurate output replica in a file in EDF format. The test also confirms that the original patient details and the loaded set-up data are correct.

The results of this test confirm that the RMX can accurately record multiple physiological signals, at a sufficient quality for later analysis by trained experts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2008

S.L.P. Limited
C/O Mr. J. G. van Vugt
Responsible Third Party Official
KEMA Quality B.V.
4377 County Line Road
Chalfont, Pennsylvania 18914

Re: K080375
Trade/Device Name: RMX Physiological Data Recorder
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: August 15, 2008
Received: August 18, 2008

Dear Mr. van Vugt:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Samuel-Lin, M.D. for

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

SECTION 4- INDICATIONS FOR USE STATEMENT

(For 510k Substantially Equivalent Determination)

510(k) Number (if known): K080375

Device Name: RMX Physiological Data Recorder

Indications for Use:

The RMX is a physiological data recorder intended to collect and record data from multiple physiological channels and additional auxiliary inputs from undesignated channels. It is indicated for use by or on order of a physician. The RMX is intended for use in a supervised (hospital) or unsupervised (home) environment.

Prescription Use __X___ AND/ OR Over the Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

510(k) Number: K080375