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510 (k) SUMMARY

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

Submitted by: Sleep Solutions, Inc.
2450 El Camino Real, Suite 101 Palo Alto CA 94306
Phone: (650) 320-8090 Fax: (650) 320-8190

Date of Summary: November 14, 2000

Device Name: Silent Night V

Device Classification Name: Ventilatory effort recorder (MNR) Class 11

Legally Marketed Devices to Which Equivalence is Claimed: The legally marketed predicate devices are the Silent Night II (K981034), the Stardust (K973902), the EdenTrace II and the SensorMedics 4000 Series (K915856). The Silent Night V was evaluated in the clinical setting in comparison to the legally marketed SensorMedics 4000 Series sleep system (K915856).

Device Description: The Silent Night V is a portable, line-powered ventilatory effort recorder, intended for use in the home for the diagnostic evaluation of sleep disorders. The device consists of a bedside unit with a cable that runs to a patient module which is positioned on the patient's arm. The sensors are positioned on the patient's body and connect into the patient module. The Silent Night V contains the same functions as its predecessor, Silent Night II, with the addition of two other functions, The functionality of Silent Night V has been expanded from the previous generation device, (Silent Night II - K981034) to include blood oxygen saturation level, pulse rate, and respiratory effort monitoring. The Silent Night V provides the following data:

- Arterial oxygen saturation level (SP02)
- Pulse rate
- Respiration effort signal
- Airflow waveform corrected for ambient room noise

Throughout a typical sleep study, sleep-disordered breathing information and statistics are stored into the memory. The stored information includes time and duration of apneas and hypopneas, blood oxygen saturation levels, pulse rate, respiratory effort level, sound intensity level, epoch numbers and paused time intervals. Current storage capacity is 512 Kbytes, which is adequate to retain three 8-hour sleep studies. Software has been developed to retrieve, score, display and print the collected data on a personal computer platform. A summary report and an event log can be provided to the physician to view the sleep data.

Intended Use: The Silent Night V is indicated for use in the diagnostic evaluation of adults with possible sleep apnea. The Silent Night V can score obstructive apneas, which includes mixed apneas.

Performance Data:
Engineering data - Silent Night V was evaluated according to appropriate standards for EMI, EMC, mechanical and environmental testing. The device is in compliance with IEC 60601-1 and IEC 801-X (for mechanical and environmental stresses) standards.

Clinical data - Silent Night V was evaluated in the clinical setting. Patients underwent a sleep laboratory evaluation with a standard polysomnograph. Silent Night V was used concomitantly for a side-by-side comparison. The number of apneas, hypopneas and the resulting Respiratory Disturbance Index (RDI) calculated by the Silent Night V was compared with the data gathered simultaneously by the standard polysomnograph. The data were compared on an event-by-event basis. The RDI scores were determined and compared with the RDI score from the PSG using the Pearson r. The correlation coefficient between the PSG and the Silent Night V was 97.7%. Using the total number of apneas as the basis for calculation, the sensitivity between the two devices for apnea detection was 83.2% and the number of false positive events per hour was 3.5 (# of false positive apneas per hour). Using the total number of events (apneas and hypopneas) as the basis for calculation, the overall sensitivity was 90.7% and the number of false positive events per hour was 3.8.

The definition for RDI is the total number of apneas and hypopneas, divided by the study duration (in hours). For RDI, using the overall number of patients as the basis of calculation, and a cut-off of RDI=15, the Silent Night V achieved a sensitivity of 95% and a specificity of 91% when compared to the PSG.

The results of the clinical study demonstrated the performance of the Silent Night V in detecting disordered breathing events, which can be indicative of sleep apnea. In view of the noninvasive, user-friendly design and simple operational features of the device, the Silent Night V offers potential benefit as a cost effective home use device for the evaluation of patients with possible sleep disorders.

Conclusion: The information and data, provided in this 510(k) notification established that the Silent Night V is substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2000

Mr. J. Scott Adams
Sleep Solutions, Inc.
2450 El Camino Real, Suite 101
Palo Alto, CA 94306

Re: K000253
Silent Night V
Regulatory Class: II (two)
Product Code: 73 MNR
Dated: October 5, 2000
Received: October 6, 2000

Dear Mr. Adams:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.0 INTENDED USE STATEMENT

510(k) Number (if known): K000253

Unknown

Device Name:

Silent Night V

Indications for Use:
The Silent Night V is indicated for use in the diagnostic evaluation of adults with possible sleep apnea. The Silent Night V can score obstructive apneas, which includes mixed apneas.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the Counter Use** _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K000253