

K981034

OCT 30 1998

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.

Submitter's Name: ^{Sleep Solutions} Local Silence, Inc.
1340 S. DeAnza Blvd., Suite 208
San José, CA 95129 USA
Contact person: Tony Matouk, Chief Operating Officer

Date of Summary: March 13, 1998

Device Name: Silent Night™ II

Device Classification Name: Ventilatory Effort Recorder (73 MNR); Class II

Legally Marketed Devices to which Equivalence is Claimed: The legally marketed predicate device is the Silent Night™ I (K963597), determined to be substantially equivalent to a legally marketed (preAmendment) device on January 23, 1997. The Silent Night II was evaluated in the clinical setting in comparison to the legally marketed Sensormedics 4000 Series Sleep System (K915856), determined to be substantially equivalent to a legally marketed (preAmendment) device on October 26, 1992.

Device Description: The Silent Night™ II is a modified version of the legally marketed Silent Night I. The device is a portable, line-powered ventilatory effort recorder intended for use in the home screening of possible sleep disorders. The metal box has two receptacle connectors: one for input power and another for the microphone cable. The sensing microphone and the ambient noise microphone are located at the distal end of the cable, and are attached to the user by means of a modified conventional plastic oxygen cannula. The sensing microphone, located directly beneath the patient's nose, senses respiratory sounds during sleep. The ambient microphone, angled to the side of the patient's nose, senses room ambient noise and measures snoring levels. The Silent Night II is capable of recording up to four nights of sleep study data. The beginning and end of the sleep study are controlled by the use of the START and STOP buttons, located on the front of the unit. An LCD indicates operational status and has a sound level bar, used by the patient at the beginning of the study to verify adequate sensing of breathing sounds by the device.

The device operates by sensing the sound field (breathing sounds + room ambient noise) via the two microphones. Breathing sounds are extracted from all sounds received. The signals are filtered, analyzed, and processed to differentiate between types of sounds and to classify sounds as regular snoring or breathing, hypopnea, or apnea. When the sleep study is completed, the cumulatively logged data are downloaded by ^{Sleep Solutions, Inc} Local Silence into a personal computer. Specialized software formats the data and provides, for each night of the sleep study, information about apneas, hypopneas, and snoring levels.

Intended Use: The Silent Night II is indicated for use in the diagnostic evaluation of adults with possible Obstructive Sleep Apnea. It is intended to record a patient's respiratory pattern. The device is designed for prescription use in home screening of adults with possible sleep disorders. The intended use of the Silent Night II is identical to that of the predicate device, the Silent Night I, and is a subset of the intended use of the legally marketed Sensormedics 4000 Series Sleep System.

Descriptive Summary of Technological Characteristics and those of Predicate Devices: The Silent Night II is a portable, line-powered device which detects and records respiratory patterns during sleep. The device components are housed in a metal box, which contains the hardware and software required for device function. The Silent Night II employs two microphones. The sensing microphone, located directly beneath the patient's nose, senses respiratory sounds during sleep. The ambient microphone, angled to the side of the patient's nose, senses room ambient noise and measures snoring levels. Sleep study data are downloaded to a computer for printing.

As with the Silent Night II, the legally marketed Silent Night I is a portable, line-powered device which detects and records respiratory patterns during sleep. An enclosure contains the device components and software required for device function. The Silent Night I also employs two microphones; however, the sensing microphone of the Silent Night I is aerial and is located 1 to 2 feet from the mouth of the patient, while the ambient microphone is built into the rear of the box. Device function and principle of operation are identical between the two devices. Respiratory sounds are differentiated by the device and classified as regular snoring or breathing, hypopnea, or apnea. In the Silent Night I, these classified events are logged cumulatively and displayed on the control panel on the top of the device.

The Sensormedics 4000 Series Sleep System is intended to collect, score and report data from sleep studies such as the electroencephalograph, electro-oculograph, electromyograph and electrocardiograph. The product is also used for recording respiratory signals from devices such as thermistors and thermocouples, and breathing sounds detected by transducers or microphones. The device is intended for use in a hospital or sleep laboratory setting.

Performance Data:

Engineering: In view of the modifications made to the Silent Night I, ^{Sleep Solutions} Local Silence, Inc. evaluated the need and requirements for additional testing of Silent Night II. With the exception of electrostatic discharge testing (which was completed with acceptable results), it was determined that due to the extensive similarities in design, materials and construction of the Silent Night II to Silent Night I, additional mechanical and environmental testing was not warranted.

Clinical: The Silent Night II was evaluated in the clinical setting. Patients were subjected to sleep laboratory evaluation with a standard polysomnograph (the Sensormedics Model 4100 Somnostar system) and the additional use of the Silent Night II. The number of Apneas and Hypopneas and resulting Respiratory Disturbance Index (RDI) calculated by the Silent Night II were compared with data gathered simultaneously on these parameters by the Sensormedics device.

Statistical analysis of the test results indicated a high positive correlation between the measurements obtained by the two devices. Further analysis indicated that there is a strong positive linear association between the measurements obtained from the two devices. Additional analyses indicated a high degree of both specificity and sensitivity.

The study results establish the efficacy of the Silent Night II in detecting Disordered Breathing Events, which can be indicative of sleep apnea or another sleep disorder. In view of the noninvasive, user-friendly design and simple operational features of the device, the Silent Night II offers potential benefit as a cost-effective home-use device for the screening of patients with possible sleep disorders.

Conclusion: The information and data provided in this 510(k) Notification establish that the Silent Night II is substantially equivalent to the legally marketed predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 30 1998

Ms. Lisa S. Jones
Sleep Solutions, Inc.
c/o Devices for the Future, Inc.
9223 Ilona Lane
Houston, TX 77025

Re: K981034
Silent Night™ II
Regulatory Class: II (two)
Product Code: 73 MNR
Dated: August 7, 1998
Received: August 10, 1998

Dear Ms. Jones:

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.

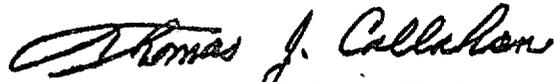
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

August 7, 1998

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510(k) Number: K981034

Device Name: Silent Night II

Indications for Use: The Silent Night II is indicated for use in the diagnostic evaluation of adults with possible Obstructive Sleep Apnea. It is intended to record a patient's respiratory pattern during sleep. The device is designed for prescription use in home screening of adults with possible sleep disorders. Information provided by the device includes the numbers of apneic and hypopneic events and the proportion of these events to the total sleep duration; and snoring levels (in decibels). The device is capable of recording four nights or up to 40 hours for an individual patient, after which time the sleep data are downloaded for provision to the prescribing physician.

(Concurrence of CDRH, Office of Device Evaluation (ODE))

Lark M. Santos 10-29-98
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

Prescription Use
(Per 21 CFR 801.109)

510(k) Number ~~Over-the-Counter Use~~ _____