K963597

JAN 23 1997

Local Silence, Inc.

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: Local Silence, Inc.
935 Fremont Avenue, Suite 115
Los Altos, CA 94024 USA
Telephone: (415) 917-9130
Contact Person: Anthony Matouk, President

Date of Summary: January 21, 1997

Device Name: Silent Night I

Device Classification: Ventilatory Effort Recorder (73 MNR)

Legally Marketed Device to Which Equivalence is Claimed: The legally marketed predicate device is the EdenTec Model 3711 Digital Recorder (K910870), determined to be substantially equivalent to a legally marketed (preAmendment) device on August 29, 1991. The Silent Night I has been evaluated in the clinical setting in comparison to the Grass Model 7P511 High Performance AC Amplifier, a standard polysomnograph recording device.

Device Description: The Silent Night I (SNI) consists of a metal box measuring approximately 23 centimeters wide by 17 centimeters deep by 7.5 centimeters high. The device is portable, line-powered and weighs approximately three pounds. The box contains the operational components of the device and has two receptacle connectors: one for input power and another for the sensing microphone. This microphone is attached to the SNI by means of an eight-foot flexible cable and connector. Another microphone is built into the rear of the box and senses room ambient noise. A POWER switch is located on the back of the unit. A switch enabling the user to PAUSE and RESUME device operation is located on the side of the unit.

The device operates as follows: the sound field (breathing sounds + room ambient noise) is sensed by the two microphones and sent to the controller, which extracts breathing sounds from all sounds received. These signals are then sent through bandpass filters and the amplitude characteristics of the signals in the frequency realm are analyzed. The signals are then processed by the pattern recognizer, which differentiates between types of sounds and classifies them as regular snoring or breathing, hypopnea, or apnea. These classified events are logged cumulatively and shown on a liquid crystal display as Disordered Breathing Events (DBE) on the front control panel of the device.

Intended Use: The Silent Night I 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 use in home screening of adults with possible sleep disorders.

The legally marketed EdenTec Model 3711 Digital Recorder is intended to record physiologic data, including heart rate, impedance respiration, snoring sounds, air flow, body position and pulse oximetry in the home or in the hospital, and may be used on pediatric or adult patients. The device also provides a printout of recorded data.

The Grass Model 7P511 High Performance AC Amplifier is intended to record bioelectric signals such as the electroencephalograph, electrooculograph, electromyograph, electrocardiograph, and respiration.

The intended use of the Silent Night I is a subset of the intended use of the EdenTec Model 3711 Digital Recorder, as the Silent Night I records and analyzes only respiratory sounds, is intended for use only in adults, is designed for use in the home, and does not contain printing capability. The intended use of the Silent Night I is also a subset of the intended use of the Grass Model 7P511 High Performance AC Amplifier, as the Silent Night I records and analyzes only respiratory sounds, rather than a variety of physiologic signals.

Descriptive Summary of Technological Characteristics and Those Of Predicate Device: The Silent Night I is a portable, line-powered device which records and analyzes breathing sounds. The device components are housed in a metal box, which contains the hardware and software required for device function. The Silent Night I employs two microphones. One microphone, placed near the patient, is attached to the SNI by means of a cable and is used to sense the patient's respiratory sounds. Another microphone is built into the rear of the box and senses room ambient noise.

The legally marketed EdenTec Model 3711 Digital Recorder is intended to record physiologic data, including heart rate, impedance respiration, snoring sounds, air flow, body position and pulse oximetry. Device hardware and software are contained in a portable enclosure. Respiratory sounds are sensed by a microphone placed near the patient. The power source is a battery charger plugged into a 3-prong 120 VAC wall outlet.

The Grass Model 7P511 High Performance AC Amplifier is intended to record bioelectric signals such as the electroencephalograph, electrooculograph, electromyograph and electrocardiograph. The product is also used for amplifying respiratory signals from devices such as thermocouples and pneumographs, and breathing sounds detected by microphones. It is a high gain, low noise AC preamplifier and polygraph pen driver amplifier in a single 19-inch module. The amplifier has nine low frequency filter selections and ten high frequency filter selections. A rear chassis connector is provided for connection to the Grass Electrode Selector Panels.

Performance Data:

Environmental: The Silent Night I (SNI) was subjected to mechanical, environmental and electromagnetic compatibility testing in accordance with the requirements of applicable standards. All test units passed visual inspection and electrical characterization, and exhibited proper operation following all mechanical and environmental test sequences. The test results demonstrate that the Silent Night I possesses a degree of mechanical integrity and durability suitable for its intended-use environment. In addition, the Silent Night I passed all electromagnetic compatibility tests without failure. The test results demonstrate that the Silent Night I operates in compliance with appropriate emissions limits and possesses a degree of immunity to the effects of electromagnetic interference adequate for operation in its intended-use environment.

Electrical Safety: Electrical safety test data were obtained in conjunction with testing required for UL (Underwriters' Laboratories) listing. The Silent Night I demonstrated acceptable design and/or performance characteristics for all electrical safety parameters evaluated.

Clinical: The Silent Night I has been evaluated in the clinical setting. Patients were subjected to sleep laboratory evaluation with a standard polysomnograph (the Grass Model 7P511 High Performance AC Amplifier) and the additional use of the Silent Night I. The number of Disordered Breathing Events (DBE) and resulting Respiratory Disturbance Index (RDI) calculated by the Silent Night I were compared with data gathered simultaneously on these parameters by the Grass polysomnograph.

Statistical analysis of the test results indicated a high positive correlation between the measurements obtained by the two devices. Further analysis indicated that the measurements are not independent: 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 I in detecting Disordered Breathing Events, which can be indicative of sleep apnea or another sleep disorder. In view of the noninvasive, non-patient contact design and simple operational features of the device, the Silent Night I offers potential benefit as a cost-effective home-use device for the screening of patients with possible sleep disorders.

Lisa S. Jones

Lisa S. Jones
Regulatory Affairs Consultant
Local Silence, Inc.

Jan. 21, 1997
Date