K012437

JUL 16 2002

DeVilbiss Sleep Recorder 510(k) Summary

Submitter's Name:	Sunrise Medical HHG Inc. Respiratory Products Division 100 DeVilbiss Drive Somerset, PA 15501-0635
Contact Person:	James P. Froehlich (814) 443-7692
Date Prepared:	July 5, 2001
Trade or Proprietary Name:	DeVilbiss Sleep Recorder
Common or Usual Name:	Ambulatory sleep recorder
DeVilbiss Model Number:	RM60
Establishment Registration Number:	DeVilbiss # 2515872
Device Class:	Class II
Classification Name:	Ventilatory Effort Recorder CFR # 868.2375 MNR

Legally Marketed Predicate Device:	**510(k) Registration #**
Bio-Logic Sleep Scan	K962103
Nellcor Puritan Bennett (Melville) Ltd. Sandman Sleep Data Storage System	K934599

Description of Device:

The DeVilbiss Sleep Recorder consists of a main control box, a chest mounted interface box and several sensors mounted to the patient. The main control box contains a Novametrix oximeter board, the microcontroller and memory board, four AA battery compartment and connectors for external devices. The main control box is intended to be placed on a night stand or near the patient's bed. A chest mounted interface box containing body position sensors and connections for a nasal thermistor, a nasal cannula, snore microphone and three ECG leads is attached to the patient. The sensors used for a standard diagnostic recording are:

1. ECG leads (3)
2. Snore Microphone
3. Nasal Thermistor or Nasal Cannula
4. Oximeter Probe
5. Body Position sensor (inside chest box)

A patient is fitted with the ECG leads for proper placement by a healthcare professional. The snoring channel is adjusted for optimum sensitivity while monitoring the patient. The patient then takes the DeVilbiss Sleep Recorder home and connects the chest box and oximeter probe to the main control box before going to bed. The recording duration is 8 hours max, unless the batteries are low. The DeVilbiss Sleep Recorder will stop recording early if necessary to conserve enough battery energy to download the recorded data.

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After the DeVilbiss Sleep Recorder data is downloaded to a PC, analysis is performed on one or more channels to determine SpO2 desaturations, heart rate shifts and Pulse Transit Time (PTT) shifts. The information in the study is hand scored for respiratory events and used by a healthcare professional to determine if CPAP treatment is a preferred approach.

Statement of Intended Use:

The DeVilbiss Sleep Recorder is a portable recording system for recording of adult sleep parameters. The basic model records oxygen saturation, airflow, chest impedance, patient body position and snoring. Pulse Transit Time (PTT) and heart rate are available as optional channels. The intended environment for use of the device is in the patient's home or within an institutional setting on the order of a physician. This device is intended to aid the physician in diagnosing adult sleep apnea. A qualified medical professional should score the device's recorded signals to determine respiratory events. The DeVilbiss Sleep Recorder or any of its components should not be used as a life support device, life support system, or as a critical component of a life support device or life support system.

General Theory of Operation:

The DeVilbiss Sleep Recorder consists of a battery powered data collection unit with sensors that monitor physiological signals. The data collection unit is connected to the sensors via a small case (chest box) that is held on the patient's chest by an elastic belt. The chest box contains a 5 position sensor for body position information, three high impedance ECG electrode inputs, an input for a snore sensor, an input for a nasal thermistor and a fitting for attaching a nasal cannula. The sensors are fitted to a patient by a medical professional and the signals are verified. Two ECG electrodes are placed on opposite sides of the chest, just below the sternum. A reference electrode is placed on the lower abdomen. The ECG leads are color coded for correct connection to the chest box. The snore sensor is attached by an adhesive ring to the side of the neck. The nasal thermistor is positioned on the upper lip, with one element located at each nostril and one extending toward the mouth. A nasal air flow signal can be obtained using a nasal cannula instead of the thermistor. A switch on the chest box selects between thermistor or cannula for the airflow signal.

Conclusion:

The performance tests and clinical trials completed on the DeVilbiss Sleep Recorder demonstrate substantial equivalence to the predicate devices based on types of sensors, battery operation, real time monitoring, presentation and analysis of the recorded data and intended use. The safety and effectiveness is demonstrated by the tests confirming accuracy of the recorded data to the product specifications and the conformance to electrical standards applied for a Class II Type CF device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2002

Mr. Jim Froehlich
Senior Project Engineer
Sunrise Medical HHG, Incorporated
Respiratory Products Division
100 DeVilbiss Drive
Somerset, Pennsylvania 15501-0635

Re: K012437
Trade/Device Name: DeVilbiss Sleep Recorder, Model RM60
Regulation Number: 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: April 19, 2002
Received: April 22, 2002

Dear Mr. Froehlich:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Anesthesiology,
General Hospital, Infection Control
and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

17.0 DeVilbiss Sleep Recorder Indications for Use Statement

510(k) Number (if known) : ~~Not known~~ K012437

Device Name: DeVilbiss Sleep Recorder

Indications for Use

The DeVilbiss Sleep Recorder is intended for screening patients suspected of or exhibiting symptoms of sleep disorders. The DeVilbiss Sleep Recorder can be used with an autotitrating CPAP to record the results of CPAP treatment for adults diagnosed with sleep apnea syndrome. Patients suffering from excessive daytime sleepiness should be referred to a sleep disorder specialist. The results of an unattended screening are insufficient to identify all possible medical disorders that may produce these symptoms. This device is intended to aid the physician in diagnosing adult sleep apnea. A qualified medical professional should score the device's recorded signals to determine respiratory events.

Contraindications

The DeVilbiss Sleep Recorder or any of its components should not be used as a life support device, life support system, or as a critical component of a life support device or life support system.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012437