APR 2 5 2003

K022294

510(k) SUMMARY:

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

Submitter's Name and Address:

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Contact Person: David T. Krausman, Ph.D.

Date Summary was prepared:

April 17, 2003

Name of Device:

Trade Name: SleepCheck

Common Name: Sleep Apnea Screening Device

Classification Name: Ventilatory Effort Recorder

Identification of predicate device:

Number: K002135, "SleepStrip", Influent Ltd.

Product Code: 73 MNR

Statement of Intended Use:

The SleepCheck is intended for use in monitoring nasal and oral airflow. The device is intended for use as a prescreening tool to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's test score.

Description of Device:

The SleepCheck is a pager-sized monitor that clips onto the patient's nightshirt. The monitor utilizes an air cannula sensor to capture the patient's nasal and oral airflow. The sensor cannula, containing 3 airflow ports, is placed under the nostrils, above the lip and held in place around the ears with a lanyard. The unit has an LCD readout that displays the total number of apneas and the apnea/hypopnea index (AHI). The LCD also flashes a warning if the sensor is improperly applied or displaced. The LCD also provides a dynamic bar graph that displays the breathing pattern. As the patient inhales and exhales, the bar moves back and forth, verifying proper sensor application and monitor operation. When breathing decreases or is interrupted for 10 seconds or longer, this event is considered an apnea episode and is tallied on the LCD readout. The patient self-applies the unit before going to bed and wears the unit through the night. Upon waking, the patient will take off the unit and return it to the physician. The physician will check the LCD to learn the number of apneas and the rate of apnea events (AHI) that occurred throughout the night. The technical validity of the test is also indicated.

Comparison Inventory:

Function:	SleepCheck	SleepStrip
Intended Use	Monitor sleep apnea events	Monitor sleep apnea events
Method of Measurement	Airflow sensor-pressure	Airflow sensor-thermal
Sensor placement site	Rests over the lip, under the nose	Rests over the lip, under the nose
Sensor elements	3 prongs - two nasal, one oral	3 prongs - two nasal, one oral
Measured variable	Oral and nasal airflow	Oral and nasal airflow
Sensor attachment	Air-cannula lanyard style	Stick-on adhesive-backed
Display type	Liquid crystal display element	Chemical display element
Breathing Indicator	Moving-bar display	Blinking-light display
Signal loss indicator	Yes, on display	Yes, on display
Apnea detection counter	254 per hour maximum	126 per hour maximum
Index scoring	AHI per sleep period	AHI per sleep period
Event score	Total apnea event count	AHI x 5 = total apnea event count
Display function	Numeric readout - decimal counter	Numeric readout - binary counter
Sleep night use	Single night monitoring	Single night monitoring
Maximum run-time	9 hours	5 hours
Controller	Microprocessor	Microprocessor
Airflow signal conditioning	Filtered and digitized	Filtered and digitized
Sampling method	Analog to digital conversion	Analog to digital conversion
Sample rate	10 per second continuous	10 per second continuous
Apnea detection criterion	Signal decrease 10 sec. or longer	Signal decrease 10 sec. or longer
Monitor application	Patient self-applies	Patient self-applies
Download	None - display readout only	None - display readout only
Physical Characteristics	Small, non-tether monitor	Small, non-tether monitor
Power	Alkaline battery	Lithium battery
Clinical Studies	Clinically tested against PSG	Clinically tested against PSG

Comparable characteristics of the SleepCheck and SleepStrip devices:

The SleepCheck and the predicate device SleepStrip (#K002135) manufactured by Influent, Ltd., are substantially equivalent in technology, function, and intended use: both wireless breathing monitors are indicated to screen patients for sleep disordered breathing; both devices use airflow sensors to detect nasal and oral airflow; both use a microprocessor to analyze airflow; both devices measure disordered breathing based on reduced air-flow; both devices use a low-power battery; and both devices have a display to show the recorded results to a physician. The major functions of both devices are to demonstrate on the display the amount of disordered breathing the patient experienced; both tools are intended as a screening device. Both the SleepCheck and SleepStrip devices have been validated in clinical studies using polysomnography.

The SleepCheck has one minor variation with respect to its predicate device: the SleepCheck airflow sensors are FDA Cleared single-use units (Pro-Tech FDA#K982293 - model #1294; or Braebon FDA#K984431 – model #0589/0588), while the SleepStrip airflow sensor is an FDA Cleared single-use thermistor unit (EPM #K9221120). The airflow signals produced by these sensors are substantially equivalent for their intended use. Please see Table 1 for a comparison of the components of the SleepCheck and the predicate device SleepStrip.

Table 1: Component Characteristics of SleepCheck & Predicate Device

	Sensor	FDA Number and Date
SleepCheck	Pro-Tech model #1294	#K982293 July 13, 1998
	Braebon model #0589/0588	#K984431 Dec. 30, 1998
SleepStrip	EPM EasyFlow	#K922112 Dec 7, 1992

Based on the information provided above and herein, the SleepCheck is substantially equivalent to the SleepStrip with respect to intended use, technological characteristics, and performance.

Biocompatibility characteristics of SleepCheck

Two components of the SleepCheck contact the wearer for the duration of the sleep period (usually 1-9 hours). Both components have been FDA cleared. The first component is the airflow sensor. The SleepCheck requires the use of either a Pro-Tech or Braebon airflow sensor (see Table 2). Both airflow sensors are clearly marked as single-use components. The second component is the casing. The ABS plastic casing of the SleepCheck is identical to the ABS plastic casing of the PAM-RL as it was approved in #K010997, Oct. 15, 2001 (see Table 2), in formulation, processing, and sterilization, and no other chemicals have been added. No adjustments have been made to either the airflow sensors or to the casing.

Table 2.0: FDA-Cleared SleepCheck Components

Part	Title	FDA Number and Date
Airflow Sensors	Pro-Tech model #1294	#K982293 July 13, 1998
	Braebon model #0589/0588	#K984431 Dec. 30, 1998
Casing	PAM-RL casing	#K010997, Oct. 15, 2001

Assessment of SleepCheck Performance Data:

In total, six clinical studies were conducted to validated the accuracy of the apnea detection technology and the functionally of the SleepCheck device against the gold standard PSG. These studies consisted of 111 sleep tests totaling 151 sleep nights. All studies were sponsored by the National Institutes of Health (#N43-NS-5-2328 – NINDS; #N43-NS-8-2328 – NINDS; #1R43HL65166-01A1 – NIHLB). The results of these studies were both submitted to NIH and presented at various National Sleep Disorder Conferences. All studies conducted both at-home and in the sleep laboratory indicated a highly positive agreement with full PSG, with high sensitivity and specificity. See Table 3. Based on these results, the apnea detection technology provided by SleepCheck measuring single oral/nasal channel airflow is substantially equivalent in performance to the gold standard PSG for the intended use as a prescreening tool to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's test score.

Table 3.0: Performance Characteristics of SleepCheck & Predicate Device

	SleepCheck[1]	Sleep Strip[2]
Sensitivity:	1.00	.97
Specificity	.88	.67
r to PSG (gold standard)	.99	.71

[1]Spiro et al. (2002) Sleep: 25(supplement), A275. [2] Lavie et al (2000) Sleep: 23(Supplement 2), A7.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

APR 2 5 2003

David T. Krausman, Ph.D.
Individual Monitoring Systems, Incorporated
1055 Taylor Avenue, Suite 300
Baltimore, Maryland 21286

Re: K022294
Trade/Device Name: SleepCheck
Regulation Number: 868.2375
Regulation Name: Ventilatory Effort Recorder
Regulatory Class: II
Product Code: MNR
Dated: January 31, 2003
Received: February 10, 2003

Dear Mr. Krausman:

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 Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Patricia Cucenita/for

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Intended Use:

The SleepCheck is a small monitor designed to assess nasal and oral airflow. Apnea breathing events are counted based on a reduction in airflow. The device is intended for use as a screening device to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's score.

Prescription Use Only ✓

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

510(k) Number: K022294