

K 111514

DEC 16 2011

1. 510(k) Summary - Basic Information

1.1 Sponsor

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Date Prepared: November 21, 2011

1.2 Device Name

Proprietary Name: SBV2™ System
Common Name: Activity Recording Device
Classification Name: GWQ, Electroencephalograph, 882.1400, Class II

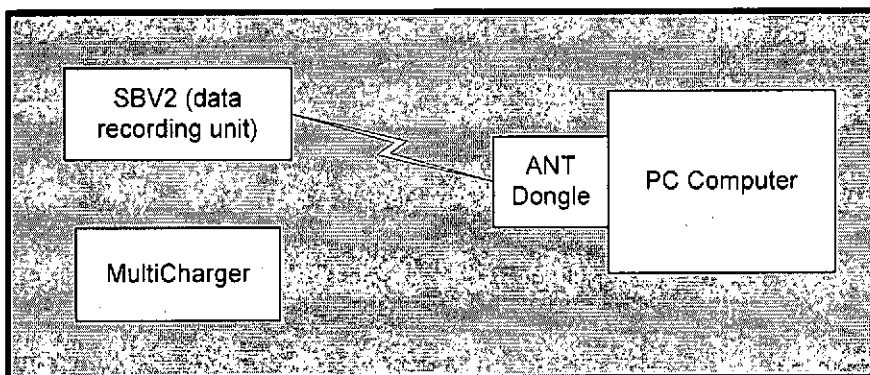
1.3 Identification of Legally Marketed Device

SBV2 is substantially equivalent to the ActiGraph device (K040554).

1.4 Device Description

The SBV2 System is a device that monitors activity. It relies on the measurement and analysis of wrist movements to detect and characterize sleep/wake periods. The device allows some aspects of sleep derived from the analysis of activity to be reported. The SBV2 System is graphically depicted in Figure 1.

Figure 1: SBV2 System Graphic Depiction



1.4.1 Components

The following SBV2 System components (depicted in Figure 1) are briefly described as follows:

- **SBV2 (Data Recording Unit)**; wristwatch-like device used to capture and store accelerometer data from user.
- **ANT Dongle**; A PC peripheral that uses a proprietary wireless protocol to transfer stored accelerometer data to SleepAnalyzer software application.
- **PC Computer**; standard PC used to host the SleepAnalyzer application.
- **MultiCharger**; coin cell battery charger used to fully charge the Data Recording Unit battery prior to use.

1.5 Intended Use

The SBV2 System is an activity monitor designed and intended for documenting physical movements associated with applications in physiological monitoring. The device's intended use is to analyze limb activity associated with movement during sleep and to extract information about certain sleep parameters from these movements. SBV2 can also be used to assess activity in any instance where quantifiable analysis of physical motion is desirable. The use of the SBV2 is indicated for adults 22 years of age and over.

1.6 Comparison to Cleared Device

SBV2 is substantially equivalent to the ActiGraph (K040554). Table 1 compares the features of SBV2 with those of ActiGraph.

Table 1: Comparison of SBV2 to ActiGraph (K040554)

Characteristic	SBV2	ActiGraph
	Usage Characteristics	
Intended Use	The SBV2 System is an activity monitor designed and intended for documenting physical movements associated with applications in physiological monitoring. The device's intended use is to analyze limb activity associated with movement during sleep and to extract information about certain sleep parameters from these movements. SBV2 can also be used to assess activity in any instance where quantifiable analysis of physical motion is desirable. The use of the SBV2 is restricted to adults 22 years of age and over.	The ActiGraph is a small limb worn activity monitor designed for documenting physical movements associated with applications in physiological monitoring. The device's intended use is to analyze limb activity associated with movement during sleep. The unit can also be used to assess activity in any instance where quantifiable analysis of physical motion is desirable.
Principle of Operation	Accelerometer used to collect actigraphy data to determine a person's activity level during the course of a day.	same
Components	<ul style="list-style-type: none"> • Data recording unit (SBV2 activity monitor) worn by patient • PC software application prepares data recording unit, retrieves collected data, and generates report. 	same
Data Collection Method	Data recording unit is attached to patient's limb or torso and worn continuously during data collection period.	same
Sampling Interval	16 Hz	1 Hz and up (web site indicates 30 Hz)
Recording Time	1 to 30 days. Typically 7 days.	2 hours to 180 days (end of battery life)

Characteristic	SBV2	ActiGraph
Data Recording Unit to PC Interface	Wireless communications using ANT protocol in 2.4 GHz ISM Band.	RS232 or USB
Commercial Distribution	Indicated for Over the Counter Use. Patient receives data recording unit from dispensing agent such as pharmacist.	Prescription Use
Reporting	Dispensing agent retrieves collected data from data recording unit and generates report based on collected data.	Same
Physical Characteristics		
Size	1.5"x1.35"x.4"	2" x 2" x 0.5" (does not include wrist band)
Weight	1 oz.	1.5 oz, with battery 2.5 oz
Battery	rechargeable 3.7V Lithium Coin Cell	same
Recharging Method	MultiCharger	connection to USB port
Accelerometer Sensitivity	2.4 milliGs	16 milliGs
Enclosure	Polycarbonate	same
Wrist Band	Santoprene	Nylon w Velcro
Moisture susceptibility	Water resistant	same
Storage Temperature	-40°C to +60°C	-10°C to +50°C
Operating Temperature	0°C to +40°C	0°C to +45°C

1.6.1 Differences between SBV2 and ActiGraph

The meaningful differences between SBV2 and the ActiGraph predicate device are their means of commercial distribution and their methods for communicating between data recording unit and PC software application.

- SBV2 is intended for Over-The-Counter commercial distribution. ActiGraph is indicated for Prescription Use.
- SBV2 uses wireless communications between its data recording unit and its PC software. ActiGraph uses hardwired serial communications.

2. Performance Information

Performance data produced by a two-phase investigation demonstrates substantial equivalence between polysomnographic sleep/wake classification and SBV2 actigraphic sleep/wake classification.

2.1 Substantial Equivalence Evaluations

The Fatigue Science SBV2 was validated against expert human actigraphy scoring and against polysomnography as a device for accurately measuring sleep/wake periods. Polysomnography is considered to be the accepted medical standard for conducting sleep evaluations. There were two phases of the evaluation. A detailed account may be found in the Fatigue Science White Paper entitled Validation of the Fatigue Science SBV2 authored by Russell, Caldwell, Arand, Myers, Wubbels, and Downs (2010).

2.1.1 Overview

The first phase of the scoring validation effort was conducted by research personnel at Archinoetics, LLC. These personnel possessed substantial expertise in the visual

examination and classification of raw actigraphy data into various states such as “awake and moving about” versus “lying quietly in bed or elsewhere”. The second phase of the classification validation effort was conducted by Dr. Donna Arand, Board Certified Sleep Specialist, Kettering Hospital; Dr. John Caldwell, Experimental Psychologist, Fatigue Science; and Dr. Chris Russell, Senior Scientist, Archinoetics, LLC; in conjunction with the Wallace Kettering Health Networks Sleep Disorders Center in Kettering Ohio.

2.1.2 Phase 1 Summary

Since the SBV2 is designed to be worn 24-hours per day for several days at a time, it was first necessary to ensure that the “up-and-about periods” could be correctly differentiated from the “lying-in-bed periods.” Using de-identified actigraph data from 180 participants, we determined the agreement between algorithmic versus human classification of actigraphy into the following states: 1) Awake and moving about, 2) In bed—Awake or Asleep, or 3) Actigraph off wrist. Results indicated that the SBV2 algorithm accurately differentiated among the 3 states of interest between 87% and 95% of the time (see Table 1).

Table 1. Identification accuracy of “up & about” vs “in bed” vs “off wrist”

AWAKE, up and about	IN BED, awake or asleep	OFF WRIST
95%	95%	87%

2.1.3 Phase 2 Summary

Since once the “in-bed” state was determined to have occurred it was of utmost importance to show correct actigraphy-based classification of sleep and wake episodes, a second study focused on the comparison between in-bed polysomnography and in-bed actigraphy. Via the collection of actigraphy data simultaneously from 50 patients undergoing polysomnographic assessment at the Kettering Sleep Disorders Center, the specificity and sensitivity of actigraphic sleep/wake assessments were determined. Results indicated that SBV2 sleep/wake classification corresponded to night-time polysomnographic findings with a sensitivity of 88% and a specificity of 55% (see Table 2).

Table 2: Classification accuracy of SBV2 vs polysomnography sleep/wake

Total accuracy	Sensitivity	Specificity
82%	88%	55%

2.1.4 Final Result

Considering that for most people the majority of *in-bed time* would be spent *sleeping*, the in-bed sensitivity (correct identification of sleep) was weighted slightly more heavily than the in-bed specificity (correct identification of wake) by averaging the “in-bed state detection” of 95% with the “in-bed-asleep detection” of 88%. ***This yielded an overall SBV2 vs polysomnography agreement level of 93%.***

2.2 Sleep Report Summary

The device allows some aspects of sleep derived from the analysis of activity to be described in a sleep report. The sleep report uses a set of parameters that describe the normal ranges for an average adult user. Any further interpretations of sleep from the report should only be performed by a qualified health care professional such as a physician with training in the normal and abnormal physiology of sleep. These normal ranges are supported by the following data.

2.2.1 Sleep Duration

The normal range of sleep duration for adults is set to 7-9 hours according to supporting data from Table 1 in Berger et al. (2005), *Sleep/wake disturbances in people with cancer and their caregivers: State of the Science, Oncology Nursing Forum, 32(6):E98-E126*. In addition, both the National Sleep Foundation and the Mayo Clinic state that 7-9 is the normal range for adults. The following table appears at <http://www.sleepfoundation.org/article/how-sleep-works/how-much-sleep-do-we-really-need>:

How Much Sleep Do You Really Need?	
Age	Sleep Needs
Newborns (0-2 months)	12-18 hours
Infants (3 to 11 months)	14 to 15 hours
Toddlers (1-3 years)	12 to 14 hours
Preschoolers (3-5 years)	11 to 13 hours
School-age children (5-10 years)	10 to 11 hours
Teens (10-17)	8.5-9.25 hours
Adults	7-9 hours

Source: National Sleep Foundation

2.2.2 Sleep Latency

The normal range of sleep latency is set to 10-20 minutes according to supporting data found in a published chapter by Kryger et al. in "Principles and practice of Sleep Medicine, 2nd edition, page 965."

2.2.3 Sleep Efficiency Range

The normal sleep efficiency range is stated as 95-80% according to supporting data found in Table 1 in Berger et al. (2005), *Sleep/wake disturbances in people with cancer and their caregivers: State of the Science, Oncology Nursing Forum, 32(6):E98-E126*; as well as in Table 2 in Bonnet and Arand (2007), EEG arousal norms by age, *Journal of Clinical Sleep Medicine, 3(3):271-274*.

2.2.4 Bedtime Deviation

There are no established norms for this measure, however it is widely considered a general good-sleep-hygiene practice to minimize the deviation in bedtimes from night to night in order to promote quality restorative sleep.

Therefore, this metric (without displaying the norm) is shown in the sleep report to present users with an assessment of how well they are following this recommended practice (of adhering to a consistent bedtime).

2.3 Obtaining References

All referenced materials will be provided to dispensers in the form of hard copies in a binder. Below is a list of included references:

- ⇒ Russel, C.A, Caldwell, J.A., et al. (2011), "Validation of the Fatigue Science SBV2." Fatigue Science White Paper.
- ⇒ Carskadon, M.A. (1994). Guidelines for the Multiple Sleep Latency Test (MSLT): A Standard Measure of Sleepiness, in Kryger et al. (eds.), "Principles and practice of Sleep Medicine," pp 962-966. Philadelphia: WB Saunders Co.
- ⇒ Berger et al., (2005). Sleep/wake disturbances in people with cancer and their caregivers: State of the Science, "Oncology Nursing Forum," 32(6):E98-E126
- ⇒ Bonnet and Arand (2007), EEG arousal norms by age, "Journal of Clinical Sleep Medicine," 3(3):271-274



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Sleep Performance D.B.A. Fatigue Science
c/o Mr. Mark Goodmand, Senior Associate
Noblit & Rueland
5405 Alton Parkway, Suite A530
Irvine, CA 92604

DEC 16 2011

Re: K111514
Trade/Device Name: SVB2 System
Regulation Number: Unclassified
Regulation Name: Sleep Assessment Device
Regulatory Class: Unclassified
Product Code: LEL
Dated: November 21, 2011
Received: November 23, 2011

Dear Dr. Downs:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

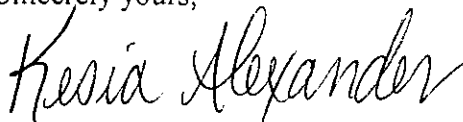
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



 Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number
(if known) K111514

Device Name SBV2 System

Indications
for Use

The SBV2 System is an activity monitor designed and intended for documenting physical movements associated with applications in physiological monitoring. The device's intended use is to analyze limb activity associated with movement during sleep and to extract information about certain sleep parameters from these movements. SBV2 can also be used to assess activity in any instance where quantifiable analysis of physical motion is desirable. The use of SBV2 is indicated for adults 22 years of age and over.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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510(k) Number K111514