DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 26, 2015

Sleep Modus, Inc.
c/o Diane Rutherford
Submissions Manager
Ken Block Consulting
1201 Richardson Drive
Suite 280
Richardson, Texas 75080-4403

Re: K143512
Trade/Device Name: ActiSpec Activity Monitor
Regulation Number: 21 CFR 890.5360
Regulation Name: Measuring Exercise Equipment
Regulatory Class: Class II
Product Code: ISD
Dated: July 30, 2015
Received: July 31, 2015

Dear Ms. Rutherford:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143512

Device Name
ActiSpec Activity Monitor

Indications for Use *(Describe)*
ActiSpec® 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

Submitter:	Sleep Modus, Inc. 1201 Richardson Drive, Suite 280-B Richardson, TX 75080
Contact Person:	Sleep Modus, Inc. Mr. Stanford P. Hudson President 1201 Richardson Drive, Suite 280-B Richardson, TX 75080 TEL: 214-405-4055 sphudson@sleepmodus.com
Date Prepared:	December 10, 2014 *(revised August 17, 2015)*
Trade Name:	ActiSpec® Activity Monitor
Common Name:	Activity Recording Device
Primary Classification Name:	Measuring exercise equipment

Product Code:	ISD	Class 2	890.5360

Predicate Devices:	K080545	ActiTrainer	ActiGraph, LLC
	K040554	ActiGraph	Manufacturing Technology, Inc.

Device Description:

ActiSpec® consists of a pair of toe bands containing firmware within the toe band housing, and an offline data download, scoring, and report generation tool. The ActiSpec® toe band is a small, battery-operated activity monitor worn on the big (great) toe. ActiSpec® typically is packaged as a pair of toe bands, one for each big toe.

ActiSpec® measures, records, and scores movements caused by the contraction of the tibialis anterior muscle responsible for movement of the big toe and dorsiflexion of the ankle and foot. These movements are detected by the accelerometer.

The intention is for the patient to wear the toe bands only while sleeping for five (5) consecutive nights. After the fifth night, the patient returns the toe bands to Sleep Modus and a report is generated for the care provider.

The generated report contains statistical information regarding the movements of the patient each night including a graph showing those movements. The report is in the form of a PDF document emailed to the care provider.

ActiSpec® has a 2-year shelf life in addition to a 120-hour active data collection period. Device activation occurs upon removal of the toe bands from the light-proof packaging.

Statement of Intended Use:

ActiSpec® 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.

Summary of Technological Characteristics:	ActiSpec® utilizes an accelerometer to monitor the occurrence of motion. The firmware utilizes a specified time base which defines an epoch. The firmware accepts notifications from the accelerometer of changes in acceleration that exceed a specified threshold. If a notification occurs within an epoch, then the firmware marks that epoch location to indicate the movement within onboard non-volatile memory. Otherwise, it marks the location to indicate that no movement occurred within that epoch. As described previously, ActiSpec® measures, records, and scores movements caused by the contraction of the tibialis anterior muscle The accelerometer is configured to notify firmware if the slope of acceleration exceeds the threshold. The accelerometer, as configured by firmware, has an effective sample rate of 10Hz and draws minimal current during non-sampling periods which enables the ActiSpec® device to achieve the 120-hour active time without requiring firmware to continually extract samples from the chip. The ActiSpec® toe band and battery are disposable with the accelerometer, microcontroller, non-volatile memory, and optical activation circuit being re-usable (recyclable) electronics. When compared to the predicate devices, all share the same indications for use, are battery operated wearable activity recording devices, feature offline scoring and data processing, share the same device category, nature of body contact and duration of contact, and are non-sterile. A few minor differences do exist between the proposed ActiSpec and the predicate devices. Most of these differences are driven by ActiSpec® being designed to be worn on the big toe while the ActiTrainer is worn on the wrist or foot and ActiGraph is worn on the wrist, ankle, or waist. Because the ActiSpec® is worn on the toe, the device is smaller and lighter. Also, the ActiSpec is to be used for one recording cycle and is worn only during sleep, so the requirements on the battery, memory, and recording time are less than that of the predicates which are typically worn for 24 hours a day for seven consecutive days. The ActiSpec shares the same acceleration sensitivity with the predicate ActiTrainer but utilizes a fixed acceleration threshold of 0.1g while the ActiTrainer allows the user to define the movement threshold. The ActiSpec has an epoch period of 0.5 seconds, which is the minimum duration of candidate movements according to standard scoring of periodic limb (foot) movements during sleep. The ActiTrainer allows for an epoch to be a minimum of 1.0 seconds to a maximum of 4 minutes. In spite of these differences, comparison testing demonstrates that the event recording capabilities of the devices are substantially equivalent.
Summary of Non-Clinical Data: Test Data:	Testing has been performed to demonstrate that the ActiSpec® meets the predetermined specifications. In addition, a bench comparison was performed between ActiSpec® and the predicate ActiTrainer device.
Conclusion:	*Sleep Modus, Inc.* considers the *ActiSpec®* to be substantially equivalent to the predicate devices listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and established medical use.

Sleep Modus, Inc. | 1201 Richardson Drive, Suite 280-B | Richardson, Texas 75080 | 214-405-4055 | www.sleepmodus.com