May 24, 2018

ActiGraph, Inc.
Brian Bell
Vice President of Quality Affairs and Regulatory Affairs
49 E Chase Street
Pensacola, Florida 32502

Re: K181077
Trade/Device Name: ActiGraph CentrePoint Insight Watch
Regulation Number: 21 CFR 882.5050
Regulation Name: Biofeedback Device
Regulatory Class: Class II
Product Code: LEL
Dated: April 20, 2018
Received: April 24, 2018

Dear Brian Bell:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181077

Device Name
ActiGraph CentrePoint Insight Watch

Indications for Use *(Describe)*
The ActiGraph CentrePoint Insight Watch is a small worn activity monitor designed for documenting physical movement associated with applications in physiological monitoring. The device is intended to monitor the activity associated with movement during sleep. The Insight watch can be used to analyze circadian rhythms and 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.

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K181077

510(k) Summary

Submitter Information

Company Name:	ActiGraph, Inc.
Contact Person:	Brian A. Bell brian.bell@actigraphcorp.com
Address:	49 E Chase St. Pensacola, FL 32502
Telephone Number:	850-332-7900 x5115
Date Prepared:	May 24, 2018

Subject Device

Trade Name:	ActiGraph CentrePoint Insight Watch
Common or Usual Name:	Sleep assessment device (actigraphy)
Classification:	Class II, Biofeedback Device 21 CFR 882.5050
Product Code:	LEL

Predicate Device

Predicate:	ActiTrainer K080545 21 CFR 890.5360, ISD (measuring exercising equipment)

Device Description

The ActiGraph CentrePoint Insight Watch is a compact, battery-operated wearable activity recording device with physical characteristics similar to those of a small wristwatch. The watch is intended to acquire and store data from an onboard accelerometer while being worn during normal activities and/or during sleep. The data record is timestamped and stored in non-volatile memory for later retrieval. Downloaded data can be post-processed based on the timestamp and magnitude of acceleration along each axis.

The housing is constructed of a combination of opaque and clear copolyesters formulated specifically for medical devices (i.e., tested and determined biocompatible), and the core data collection sensor is a 3-axis microelectromechanical system (MEMS) accelerometer. A charging dock connected to a USB power source is used to charge the device battery and communicate with a PC or peripheral.

Intended Use

The CentrePoint Insight Watch is a small wrist-worn activity monitor designed for documenting physical movement associated with applications in physiological monitoring. The device is intended to monitor the activity associated with movement during sleep. The CentrePoint Insight Watch can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.

Comparison of Technological Characteristics with Predicate

The ActiGraph CentrePoint Insight Watch is a compact, battery-operated wearable activity recording device with physical characteristics similar to those of a small wristwatch. The watch is intended to acquire and store data from an onboard accelerometer while being worn by the end user during normal activities and/or during sleep. The subject device includes a dock accessory which is required to charge the watch. Table 1, below, includes a comparison of the predicate and subject devices.

Table 1

Characteristic	Predicate Device K080545	Subject Device K181077
Indications for Use (Identical)	**Rx Only** A small worn activity monitor designed for documenting physical movement associated with applications in physiological monitoring. The device is intended to monitor the activity associated with movement during sleep. Can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.	Same
Materials of Construction	Polycarbonate (housing) Nylon & Velcro® (wrist band)	Different; Combination Copolymer (housing) Silicon (wrist band), conforms to 10993-1 Fourth edition 2009-10-15
Power Source	Lithium Ion Battery Rechargeable via USB	Same
Accelerometer Type	Microelectromechanical system (MEMS)-based integrated circuit	Same
Accelerometer Sampling Rate	30 Hz, Analog method	Different: Digital method, 32 Hz – 256 Hz
Accelerometer Dynamic Range	+/- 5 g	+/- 8 g
Firmware	Embedded C	Embedded C (updated version)
Wireless Communications Interface	Polar® module	Different: Bluetooth® Low Energy; conforms to AAMI / ANSI / IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests and IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic

		Disturbances – Requirements And Tests.
Memory	1024kB	512 MB
Heart Rate	BPM	Same
Accelerometer Sensitivity	4 milli-g per Least Significant Bit	Different; 2.4 milli-g per Least Significant Bit
Storage Temperature	-10 °C to 50 °C	Same
Operating Temperature	0 °C to 40 °C	Different; -10°C to 55°C (discharging) 0°C to 45°C while charging
Water Resistance	IP21 (condensation)	Minimum IP57 (1m for 30 minutes)
Weight	51 grams	33 grams
Size	Width: 3.37 in (85.6 mm) Height: 1.5 in (38.1 mm) Thickness: 0.6 in (15.2 mm)	Width: 1.41 in (35.8 mm) Height: 1.97 in (50.1 mm) Thickness: 0.41 in (10.5 mm)
Recording Time @ 1 min. Epoch	14 days	30 days

Technological and Performance Characteristics

The subject device, Insight Watch, includes the same fundamental technology and functionality of the predicate device, ActiTrainer, by monitoring activity using a three-axis accelerometer.

In this Special 510(k) Submission, the objective of the modification is to reduce the overall dimension to those of a wrist watch. To achieve this size reduction, the USB A-Type male connector was replaced with pins that contact a separate charging dock.

The CentrePoint Insight Watch incorporates several sub-component upgrades resulting from electronic component obsolescence, as the predicate was designed 10 years. However, this does not change how the product is intended to be used or its fundamental design and principle of operation.

The similarities to the predicate ActiTrainer device are:

- Same intended use and indications for use by way of accelerometry and heart rate monitoring (i.e., monitor for non-specific activity and motion)
- Same fundamental scientific technology characteristics
    - Utilize a microelectromechanical system (MEMS) accelerometer to measure movement
    - Leverage a microcontroller to sample and store data from the MEMS accelerometer

    - Contain digital memory to store the sampled data
    - Utilize USB technology to offload stored data and recharge the lithium battery
    - Same power source, a rechargeable lithium battery
- Same operating principle
- Incorporate the same basic design (small wearable)

Non-Clinical Testing in Support of Substantial Equivalence and Device Performance
The following bench testing was conducted to support a determination of substantial equivalence to the predicate and to demonstrate performance. The non-clinical bench tests included:

- Performance and reliability testing
- Comparative data analysis
- Basic safety and essential performance in accordance with AAMI ES60601
- Electromagnetic compatibility (EMC) in accordance with IEC 60601
- Biocompatibility and material standards confirms there is no harm to the patient wearing the device.
- System compatibility with ActiGraph software for data download and collection

Conformance to Recognized Voluntary Consensus Standards
Standards to which the subject device conforms are outlined below:

Body	Standard ID	Standard Title
IEC	60601-1-2	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances – Requirements And Tests.
ANSI AAMI ISO	14971:2007/(R)2010 (Corrected 4 October 2007)	Medical devices - Applications of risk management to medical devices
AAMI ANSI ISO	60601-1-2	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
ISO	10993-1 Fourth Edition 2009-10-15	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]
IEC	62133 Edition 2.0 2012-12	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications [Including: Corrigendum 1 (2013)]
ISO	15223-1 Edition: 3, Corrected version: 2017-03	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

Body	Standard ID	Standard Title
IEC	60529; Edition: 2: 1989 consolidated with amendment 1:1999	Degrees of protection provided by enclosures

Clinical Testing

This premarket submission did not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

Conclusion

Through the comparison of technological and performance characteristics, the proposed device found to be substantially equivalent to the predicate device.