June 23, 2023

ActiGraph, LLC
Brian Bell
VP of Regulatory
70 North Baylen Street, Suite 400
Pensacola, Florida 32504

Re: K231532
Trade/Device Name: ActiGraph LEAP activity monitor (ActiGraph LEAP)
Regulation Number: 21 CFR 882.5050
Regulation Name: Biofeedback Device
Regulatory Class: Class II
Product Code: LEL
Dated: May 25, 2023
Received: May 26, 2023

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Patrick Antkowiak -S

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231532

Device Name
ActiGraph LEAP activity monitor (ActiGraph LEAP)

Indications for Use *(Describe)*
The ActiGraph LEAP™ 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 ActiGraph LEAP™ 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.

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Special 510(k) Summary K231532

Contact Details

Applicant Name	ActiGraph, LLC
Applicant Address	70 North Baylen Street, Suite 400 Pensacola FL 32504 United States
Applicant Contact Telephone	8503327900
Applicant Contact	Mr. Brian Bell
Applicant Contact Email	brian.bell@theactigraph.com

Device Name

Device Trade Name	ActiGraph LEAP activity monitor (ActiGraph LEAP)
Common Name	Biofeedback device
Classification Name	Device, Sleep Assessment
Regulation Number	882.5050
Product Code	LEL

Legally Marketed Predicate Devices

Predicate #	**Predicate Trade Name (Primary Predicate is listed first)**	**Product Code**
K181077	CentrePoint Insight Watch	LEL

Device Description Summary

The ActiGraph LEAP™ is a wrist-worn wearable device intended to continuously record high resolution digital acceleration data associated with a patient's physical movement. In practice, a healthcare professional or researcher can prescribe the device to collect physiological data from patients in applications where quantifiable analysis of physical motion is desirable. Having physical characteristics like those of an electronic wristwatch, the device is set to collect data by the healthcare professional then placed on the subject's wrist. The device is designed to be worn during normal activities and/or during sleep over a period of days to weeks. The patient does not need to interact with the device to control the operation or data collection. The data stored on the device can be downloaded via USB or Bluetooth Low Energy and made accessible to healthcare professionals or researchers for further analysis.

The ActiGraph LEAP™ device will be supported by accessories for recharging the battery and transferring data from the device. A USB Charging Dock with a three-foot USB A cable for both charging and data transfer to a PC using the supplied communication software. The USB Charging Dock connects to the recessed electrical contacts on the back of the device. An off-the-shelf international Wall Mount AC Adapter is also supplied for optional wall charging. The USB Charging Dock can be plugged into the Wall Mount AC Adapter's USB A port for charging the device.

The device uses a high-resolution digital accelerometer to accurately measure linear accelerations in 3-axes associated with the patient's physical movement. The accelerometer technology is a microelectromechanical system (MEMS) implemented as an integrated circuit. The accelerometer data is converted to a digital representation on the MEMS accelerometer and then recorded, with timestamp, to the device's on-board memory. The memory is an 8 Gb serial NAND flash capable of storing 30 days of

accelerometer data under the default operating mode. The sample rate of the accelerometer is configurable at the following rates: 32Hz, 64Hz, 128 Hz and 256Hz.

The LCD display indicates the battery level, current functional state of the device, and date and time. The device has a 30-day battery life under the default operating mode and can be charged using the USB Charging Dock accessory. The display does not provide feedback to the wearer/patient regarding data measures. There is a simple button on the side used to turn on the display so the wearer can read the date/time and button presses are recorded in the log.

The device firmware executes on internal processors to control the device operations, display, and external communication protocols. The accelerometer sensor data can be downloaded from the device either via USB (using the dock) or via Bluetooth Low Energy.

Intended Use / Indications for Use

The ActiGraph LEAP™ 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 ActiGraph LEAP™ can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.

Indications for Use Comparison with the Predicate(s)

The subject device has the same intended use and indications for use as the predicate device CentrePoint Insight Watch (K181077).

Technological Comparison with the Predicate(s)

The following physical and technological characteristics are **changes** from the predicate device:

- The geometric outline dimensions of the device have changed for aesthetic purposes. The device body has a smaller area, mostly due to the height change from 50.1 mm to 39 mm and the device is thicker by 1.8 mm. These changes do not raise different questions of safety and effectiveness.
- The device enclosure materials have been updated to modern compositions used in similar wearable devices. The materials will have contact with intact skin for durations which may exceed 24 hours; therefore, they have been evaluated for cytotoxicity, sensitization, and irritation as applicable per the FDA Guidance Document on biocompatibility and the use of the ISO 10993-1 standard. This difference does not raise different questions of safety and effectiveness. The methods and results of the biocompatibility testing demonstrate substantial equivalence to the predicate.

A subject-predicate comparison is provided as Table 1 to demonstrate substantial equivalence in a tabular format.

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Table 1. Comparison to the predicate device K181077.

Characteristic	Predicate Device ActiGraph CentrePoint Insight Watch (K181077)	Subject Device ActiGraph LEAP™	Comparison
Indications for Use Statement	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.	The ActiGraph LEAP™ device 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 device can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.	Same; Device name has changed
Anatomical Site	Wrist	Wrist	Same
Prescription Use Only or OTC	Prescription Use Only	Prescription Use Only	Similar
User Interface	Device display indicates battery level, functional status, and time of day. No data measures or feedback to patient.	Device screen shows battery level, functional status, and time of day. No data measures or feedback to patient.	Same
Outlines Dimensions	Width: 35.8 mm (1.41 in) Height: 50.1 mm (1.97 in) Thickness: 10.5 mm (0.41 in)	Width: 38.5 mm (1.52 in) Height: 39 mm (1.54 in) Thickness: 12.3 mm (0.48 in)	Different
Display Type	LCD Display	LCD Display	Same
Energy Source	Battery	Battery	Same
Battery Type	Rechargeable Lithium-Ion	Rechargeable Lithium-Ion	Same
Battery Charger	USB Charging Dock	USB Charging Dock	Same
Principle of Operation – Technology	A microelectromechanical system (MEMS) accelerometer to measure linear accelerations associated with human body movement and record data into non-volatile memory. Specs: 3-axis, 32-256Hz, +/- 8g	A microelectromechanical system (MEMS) accelerometer to measure linear accelerations associated with human body movement and record data into non-volatile memory. Specs: 3-axis, 32-256Hz, +/- 8g	Same
Patient Skin Contacting Material	Housing: Plastic polymer Lens: Hardened glass Band and buckle: Silicon and plastic polymer	Housing: Plastic polyamide (Chendong PA+50%GF CP9021 F60LW BK3027F) Lens: Hardened glass (Caihong CG01pro+ high aluminosilicate glass) Strap (band) and buckle: Silicon (Midgold GF2041E) and Plastic polyamide (Chendong PA+50%GF CP9021 F60LW BK3027F) Bottom case lens: Nylon	Different; Biocompatibility testing has been submitted to account for this change.
Software / Firmware	Embedded firmware for microcontroller which does not connect to the internet. Communication software for data transfer.	Embedded firmware for microcontroller which does not connect to the internet. Communication software for data transfer.	Same

ActiGraph

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Characteristic	Predicate Device ActiGraph CentrePoint Insight Watch (K181077)	Subject Device ActiGraph LEAP™	Comparison
Sterility	Supplied and used non-sterile	Supplied and used non-sterile	Same
Storage and Transport Environment	Temperature: -20C to +55C Relative Humidity: 15% to 90%	Temperature: -20C to +55C Relative Humidity: 15% to 90%	Same
Operating Environment	Temperature: -10C to +55C Relative Humidity: 15% to 90%	Temperature: 0C to +55C Relative Humidity: 15% to 90%	Same

Non-Clinical Test Summary & Conclusions

The device enclosure, dimensions, and materials have been updated to modern compositions used in similar wearable devices. The materials are intended to have contact with intact skin for durations which may exceed 24 hours; therefore, they have been evaluated for cytotoxicity, sensitization, and irritation per the FDA guidance on biocompatibility and the use of the ISO 10993-1 standard. Clinical testing is not applicable to this submission.

The following technological characteristics of the device are the same as the predicate (cleared with the predicate device):

- The principle of operation is the same. A microelectromechanical system (MEMS) accelerometer is used to measure movement.
- The accelerometer data is converted to a digital representation on the MEMS accelerometer and then recorded, with timestamp, to the device's non-volatile memory.
- The LCD display on the subject device indicates the battery level, the current functional state of the device, and date and time. This is the same as predicate device.
- The LCD display on the subject device does not provide feedback to the wearer/patient regarding data measures. This is the same as predicate device.
- The power source is the same as the predicate device, a rechargeable lithium battery.
- The physical characteristics are the same, a wrist-worn device, like an electronic watch.
- Data stored on the device can be downloaded via USB or Bluetooth Low Energy.
- The software has not changed

The methods and results demonstrate substantial equivalence to the predicate (K181077), as this difference in material does not raise different or new questions of safety and effectiveness. The tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate (K181077). Therefore, the subject device is substantially equivalent to the predicate device.