April 16, 2025

PneumoWave, Ltd
Stuart Kelly
Director of Engineering & Chief Technical Officer
Suites 3 and 4, Second Floor, Maxim 3
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United Kingdom

Re: K243513
Trade/Device Name: DCM (PW-DCM)
Regulation Number: 21 CFR 882.5050
Regulation Name: Biofeedback Device
Regulatory Class: Class II
Product Code: LEL
Dated: March 14, 2025
Received: March 17, 2025

Dear Stuart Kelly:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jay R. Gupta -S

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)*
K243513

Device Name
DCM (PW-DCM)

Indications for Use *(Describe)*
DCM 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.

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

DCM is indicated for monitoring of adult patients only.

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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510(k) Summary

March 14, 2025

Submitter Information:

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Contact:

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Device Information:

Proprietary Name: DCM
Common Name: Movement Assessment Device
Classification Name: Biofeedback Device
Classification Codes: LEL
Regulation Number: 21 CFR §882.5050

Predicate Devices:

Actigraph LEAP (K231532)
Actigraph, LLC

Indications for Use:

DCM 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.

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

DCM is indicated for monitoring of adult patients only.

Device Description:

DCM 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 during sleep and in applications where quantifiable analysis of physical motion is desirable.

The device is set up 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 data collection.

The data stored on the device can be transmitted to the cloud for storage, and made accessible to healthcare professionals or researchers for further analysis. Downloaded data can be post-processed based on the timestamp and magnitude of acceleration along each axis.

The DCM system comprises a system of components:

- wearable biosensor (PW010)
- off the shelf mobile device (PW030) running the DCM mobile app (PW400)
- cloud-based data storage and data processing (PW100) (back-end)
- investigator dashboard (PW500) accessed through a web browser (front-end)

Comparison to the Predicate:

The table below compares the DCM device to the Actigraph LEAP (K231532).

	Subject Device: DCM	Predicate: Actigraph Leap (K231532)	Comments
Indications for use	DCM 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. DCM can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable. DCM is indicated for monitoring of adult patients only.	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.	Equivalent
Intended patient population	Adult	Adult	Equivalent Not intended for paediatric use
Prescription or OTC	Prescription	Prescription	Equivalent
Classification & Product code	882.5050, LEL	882.5050, LEL	Equivalent
Where device is worn (anatomical site)	Wrist	Wrist	Equivalent
What the device measures	Physical activity	Physical activity	Equivalent

	Subject Device: DCM	Predicate: Actigraph Leap (K231532)	Comments
Use during rest/motion	During motion and at rest	During motion and at rest	Equivalent
Spot checking / continuous measurement	Continuous measurement	Continuous measurement	Equivalent
Real time monitoring / retrospective evaluation	Retrospective	Retrospective	Equivalent
Operating principle	Measurement of linear accelerations in 3-axes associated with the patient's physical movement.	Measurement of linear accelerations in 3-axes associated with the patient's physical movement.	Equivalent
Biosensor sensor type	Triaxial MEMS accelerometer	Triaxial MEMS accelerometer	Equivalent
Biosensor sensitivity/resolution	0.061mg/LSB	3 mg/LSB	Equivalent: Similar range
Biosensor dynamic range	+/-2 g	+/-8 g	Equivalent: Similar range
Biosensor frequency	12.5Hz	32-256Hz	Equivalent: Similar range
Battery	Lithium coin-cell battery [CR2032]	Lithium rechargeable battery, max 4.2V	Equivalent: Both lithium batteries
Mounting components	Biosensor is mounted on an EKG electrode (Vermed A10005SG (Nissha Medical) or Skintact FS-40 (Leonhard Lang GmbH) which can be placed directly on the wrist, or attached to a wrist strap	Armband/strap	Equivalent: Biosensor can be mounted in the same way as predicate.

	Subject Device: DCM	Predicate: Actigraph Leap (K231532)	Comments
Skin contacting material	Biosensor: PC/ABS plastic EKG Electrode fixation patch: PET foam with acrylate skin adhesive (off the shelf EKG electrode)	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	Equivalent: All skin contacting materials are biocompatible polymers.
Software and firmware	Mobile app is pre-loaded onto an off the shelf mobile device. The mobile app sends data to the cloud. The health care professional accesses a web-based dashboard for data transfer.	Embedded firmware for microcontroller which does not connect to the internet. Communication software for data transfer.	Equivalent
User interface	Mobile app screen shows battery level, functional status and time of day. No data measures or feedback to patient (Health care professionals can access the web-based dashboard).	Device screen shows battery level, functional status, and time of day. No data measures or feedback to patient.	Equivalent
Sterility	Supplied non-sterile	Supplied non-sterile	Equivalent
Respiratory rate measurement	None	None	Equivalent
Apnea claims	None	None	Equivalent
Alarms / Alerts	None	None	Equivalent

Summary of Testing

The 510(k) summary of the primary predicate device does not include detailed information on testing that would allow for comparison. However, other biofeedback devices such as MotionWatch (K132764) include testing information similar to the table below that summarizes tests performed to establish the safety and effectiveness of DCM.

Requirement	Test Method	Pass/Fail Criteria	Result
The system shall measure acceleration with accuracy of 5% or better (at 1g), in 3 orthogonal directions with sensitivity to at least 0.005g	Bench testing with the biosensor in a range of orientations.	Acceleration recorded by the device meets the requirements. Accelerometer accuracy to be tested across extended duration data collection runs to confirm that there is no sensor drift.	PASS
The system shall capture sensor data with timing accuracy within ±10 seconds per hour	Bench testing with mobile app paired to biosensor for the length of a typical session, timestamps inspected.	Data is transmitted to the cloud and the timestamps are visible and accurate within the requirements when viewed in the Investigator Dashboard.	PASS
In case of connectivity issues, data is stored on the device until it can be transferred.	Bench testing with mobile app paired with biosensor, manual interruption and restoration of connectivity, followed by inspection of data.	Data is stored on the biosensor when connection to the mobile device is interrupted and transferred when connection is restored. Data is stored on the mobile device when connection to the cloud platform is interrupted and transferred when connection is restored.	PASS
Usability	Usability complies with the requirements of IEC 62366-1 in relation to safety	Usability activities are conducted according to the IEC 62366-1 process and demonstrates that the usability of the medical device is acceptable with regard to safety	PASS

Requirement	Test Method	Pass/Fail Criteria	Result
Packaging	Testing to confirm that the packaging design and construction is suitable to protect the system components during exposure to typical shipping stresses and rough handling.	Device meets visual inspection criteria and passes functional tests following exposure to typical shipping stresses and rough handling	PASS
EMC	EMC testing per IEC 60601-1-2 and 47 CFR Part 15 Subpart B.	Device meets requirements for emissions (Class B) and immunity	PASS
Wireless Coexistence	Wireless coexistence testing per ANSI C63.27	No interruption to wireless data connections.	PASS
Radio Frequency	Radiated Spurious Emissions testing per 47 CFR 15.247	Device meets requirements for spurious emissions.	PASS
Electrical Safety	Testing to verify applicable clauses of IEC 60601-1 and IEC 60601-1-11 safety standards	Device meets applicable requirements for electrical, mechanical and thermal safety, for healthcare and home use environments.	PASS
Software verification and validation	Software developed and tested per IEC 62304	Software developed and maintained in accordance with the IEC 62304 lifecycle process, and all verification and validation test passed	PASS

Clinical Testing

DCM did not require clinical studies to support substantial equivalence to the predicate device. Non-clinical and human factors testing results indicate that the device meets user needs and that it is safe and effective for its intended use.

Conclusions

DCM is substantially equivalent to the predicate device with respect to intended use, design features, technological characteristics, and performance criteria. All predetermined pass/fail criteria were met.