July 31, 2025

Ambulatory Monitoring, Inc.
Paul Chen
CTO
731 Saw Mill River Road
Ardsley, New York 10502

Re: K251574
Trade/Device Name: Sleep Watch
Regulation Number: 21 CFR 882.5050
Regulation Name: Biofeedback Device
Regulatory Class: Class II
Product Code: LEL
Dated: May 22, 2025
Received: May 22, 2025

Dear Paul Chen:

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)*
K251574

Device Name
Sleep Watch

Indications for Use *(Describe)*
A 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 and make estimates of sleep quantity/quality using accelerometry, based on actigraph algorithms designed specifically for the device's unique signal processing techniques. Can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.

The results of the processed data are graphical and numerical presentations and reports of sleep latency, sleep duration, sleep quality and circadian rhythms for the use by or on the order of physicians, trained technicians, or other healthcare professionals.

The Sleep Watch System is intended for use on a general-purpose computing platform, it does not issue any alarms. The Sleep Watch System is intended for use in the natural environment for passive, noninvasive, data collection of physiological parameters that will later be transmitted to a SaaS platform for remote review by a clinician. The Sleep Watch® device is intended for use in children and older.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary

Prepared in accordance with 21 CFR 807.92

1. Submitter

Name:	Ambulatory Monitoring Inc.
Contact Person:	Paul Chen
	paul.chen@ambulatory-monitoring.com
Address & Phone:	731 Saw Mill River Road
	Ardsley, NY 10502
Phone:	914 693 9240
Date:	June 30, 2025

2. Subject Device

Device Name:	Sleep Watch®
Model Number:	V1.0
Common Name:	Device, Sleep Assessment
Regulation Number:	21 CFR 882.5050
Regulation Name:	Biofeedback Device
Regulatory Class:	2
Product Code:	LEL
Review Panel:	Neurology

3. Predicate Device

Predicate Device	Device Name	Submitter	Product Code	510(k) Number
Primary	Wrist Actigraph	Ambulatory Monitoring, Inc.	LEL	K854030

The predicate devices have not been subject to a design-related recall.

4. Device Description

The Sleep Watch® is a wrist-worn device that monitors activity, temperature, and light exposure, it can be used to analyze sleep quantity and quality, circadian rhythms, automatically collect and store data for sleep parameters, and assess activity, intended for use by or on the order of a Healthcare Professional to aid in the evaluation of sleep disorders based on Actigraphy recordings, typically collected during sleep.

The results of the processed data are graphical and numerical presentations and reports of sleep latency, sleep duration, sleep quality and circadian rhythms for the use by or on the order of physicians, trained technicians, or other healthcare professionals.

The Sleep Watch System is intended for use on a general-purpose computing platform; it does not issue any alarms.

The Sleep Watch® system consists of:

- The Sleep Watch® built-in with accelerometer, gyroscope, PPG, temperature, and light sensors, as well as BLE and WiFi chips.
- The Sleep Watch® collects raw data from each sensor.
- The Sleep Watch® processes signals with filters and stores raw data in eMMC storage.
- Psychomotor Vigilance Task (PVT)
- An App manages Sleep Watches
- A web Application Programing Interface (API) to allow authenticated users to upload data collected form Sleep Watch® to AMI Cloud Platform
- A database to store the input, intermedium output, final output and associated data.
- A web-based database API to access the database and get outputs.
- A dashboard, a web-based user interface, to display, retrieve, manage, edit, verify, and summarize Sleep Watch® outputs.
- Proprietary algorithms to analyze actigraphy.
- A reporting API to generate sleep reports.

The Sleep Watch System is intended for patients in the home environment for passive, noninvasive, data collection of physiological parameters that will later be transmitted to a SaaS platform for remote review by a clinician. The Sleep Watch® device is intended for use in children and older.

The Sleep Watch System measures and records:

- PPG (Red, Green, Infrared) raw data
- Accelerometer (X, Y, X) and Gyroscope (Vx, Vy, Vz) raw data
- Light (R, G, B) data
- ZCM (Zero Crossing Mode)
- PIM (Proportional Integrating Measure)
- Estimate Sleep and Wake
- PVT test results
- Skin Temperatures
- MESOR (Midline Estimated Statistic of Rhythm), amplitude, and acrophase

The Sleep Watch allows for on-wrist and/or in-App rating scales (0 to 10), with experimenter selectable initial value (0,5,10) and/or questionnaires (each limited by the constraints of readability). These features should be on-demand, according to an experimenter's selected schedule, or both.

The Sleep Watch device does not provide physiological alarms.

5. Indications For Use

A 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 and make estimates of sleep quantity/quality using accelerometry, based on actigraph

algorithms designed specifically for the devices unique signal processing techniques. Can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.
The results of the processed data are graphical and numerical presentations and reports of sleep latency, sleep duration, sleep quality and circadian rhythms for the use by or on the order of physicians, trained technicians, or other healthcare professionals.
The Sleep Watch System is intended for use on a general-purpose computing platform; it does not issue any alarms.
The Sleep Watch System is intended for use in the natural environment for passive, noninvasive, data collection of physiological parameters that will later be transmitted to a SaaS platform for remote review by a clinician. The Sleep Watch® device is intended for use in children and older.

6. Summary of Technological Characteristics

The subject device (Sleep Watch) and the predicate device (Wrist Actigraph) have the same technological characteristics in actigraphy: both collect and analyze accelerometry for assessing sleep quantity and quality and circadian rhythms.

Technological Characteristics Comparison:

Elements	Predicate Device Wrist Actigraph K854030	Subject Device Sleep Watch
Classification	LEL, Biofeedback device	LEL, Biofeedback device
Indications for use	A 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 and make estimates of sleep quantity/quality using accelerometry alone, based on peer-reviewed algorithms designed specifically for the devices unique signal processing techniques. Can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.	A 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 and make estimates of sleep quantity/quality using accelerometry alone, based on proprietary algorithms designed specifically for the devices unique signal processing techniques. Can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable. The results of the processed data are graphical and numerical presentations and reports of sleep latency, sleep duration, sleep quality and circadian rhythms for the use by or on the order of physicians, trained technicians, or other healthcare professionals. The Sleep Watch System is intended for use on a general-purpose computing platform, it does not issue any alarms.

		The Sleep Watch System is intended for use in the natural environment for passive, noninvasive, data collection of physiological parameters that will later be transmitted to a SaaS platform for remote review by a clinician. The Sleep Watch® device is intended for use in children and older.
Intended Use	Analyze circadian rhythms and assess activity data acquired during sleep.	Analyze circadian rhythms and assess activity data acquired during sleep.
Patient population	Children and older	Children and older
Environment of use	Home environment	Home environment
Accelerometer	Yes	Yes
Gyroscope	No	Yes
PPG	No	Yes
Light Sensor	Yes	Yes
Temperature	Yes	Yes
PVT	Yes	Yes
ZCM	Yes	Yes
PIM	Yes	Yes
Estimate sleep/wake	Yes	Yes
BLE	No	Yes
Wi-Fi	No	Yes
Parameter Sampling Frequency	Continuous measuring and recording actigraphy data	Continuous measuring and recording of physiological data
Standards Compliance	N/A	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-1 -6 ISO 80601-2-61 ISO 10993-1
User Interface	Wristwatch	Wristwatch
Power source	Removable Battery	Internal rechargeable batteries
Data Communication	Infrared	Wi-Fi and/or App (Bluetooth) to AMI SaaS platform

Type of Protection	Type BF	Type BF
Patient contacting materials	Stainless steel and plastic	Glass lens and Plastic
Biocompatibility	Compliant to ISO 10993-1	Compliant to ISO 10993-1
Physical Characteristics	Wristwatch	Wristwatch
Cybersecurity	Authentication controls, access controls, software distribution controls.	Authentication controls, authorization controls, cryptographic controls, access controls, checksum controls, software distribution controls, intrusion detection system controls, network and systems controls, and database controls.

7. Performance Data

Ambulatory Monitoring conducted the necessary non-clinical testing and bench testing on the Sleep Watch with past results supporting the determination of substantial equivalence. Performance testing and activities that were conducted included the followings:

- Software verification and validation which included software code reviews, automated testing, acceptance testing and labeling review.
- Design traceability confirms all requirement tracing is complete from design inputs to verification/validation and that all risk controls are implemented.
- Design verification testing which confirmed that all software requirements are developed as expected
- Design validation testing which simulated the intended use to confirm that the end-to-end functionality of the Sleep Watch in conjunction with the actigraphy algorithms meets the design requirements
- A cybersecurity and data security testing were conducted to verify that data and patient protected health information security measures are thoroughly included in the design of the software.

Non-clinical Testing

Safety and performance of the Sleep Watch have been verified and validated through system testing and verification. Software development and testing were performed in accordance with *"IEC 62304:2006/A1:2015, Medical Device Software – Software life cycle processes"*. Risk has been assessed in accordance with "*ISO 14971:2007, Medical Devices – Application of Risk Management to Medical Devices"*. During software testing, all pre-defined acceptance criteria for the Sleep Watch were met and all software test cases passed. The same verification and validation methodology, risk assessment and acceptance criterion were used for predicate device.

Bench Testing

The Sleep Watch was designed, evaluated, and validated in accordance with current FDA-recognized standards, including:

- ANSI/AAMI ES60601-1 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- 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
- IEC 60601-1-11 Medical Electrical Equipment Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment
- AAMI TIR69 Technical Information Report Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems
- ANSI/IEEE C63.27 American National Standard for Evaluation of Wireless Coexistence
- IEC 62304 Medical Device Software – Software Life Cycle Processes
- AIM 7351731 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers
- ANSI/UL 2900-2-1 First Edition 2017 – Standard for Safety, Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems
- IEC 81001-5-1 Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle

The results of the system and performance testing validate that the Sleep Watch meets its requirements, performs as intended, and is as safe and effective as the predicate device. No new or different questions of safety or effectiveness have been raised.

8. Conclusion

The Sleep Watch is as safe and effective as the predicate device. Based upon the results of the system verification and validation testing, it was determined the Sleep Watch was substantially equivalent to the predicate device.