June 17, 2024

Arbor Medical Innovations, LLC
% Kay Fuller
President & Principal Regulatory & Clinical Affairs Consultant
Medical Device Regulatory Solutions, LLC
230 Collingwood Dr., Suite 260
Ann Arbor, Michigan 48103

Re: K233987
Trade/Device Name: Veraband™
Regulation Number: 21 CFR 882.5050
Regulation Name: Biofeedback Device
Regulatory Class: Class II
Product Code: LEL, ISD
Dated: May 10, 2024
Received: May 13, 2024

Dear Kay Fuller:

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.

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,

FDA 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)*
K233987

Device Name
VERABAND

Indications for Use *(Describe)*
The VERABAND™ is a compact, lightweight, body-worn activity monitoring device designed to document physical movement associated with applications in physiological monitoring. The device is intended to monitor limb or body movements during daily living and sleep for a limited time interval (up to 30- days).

The VERABAND™ can be used to assess activity in any instance where quantifiable analysis of physical motion is desired. VERABAND™ is not intended for diagnostic purposes.

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

Arbor Medical Innovations, LLC

VERABAND™

June 11, 2024

The following summary is provided pursuant to Section 513 (I) (3) (A) of the Federal Food Drug and Cosmetic Act:

1. GENERAL INFORMATION

Submitter Information:
Arbor Medical Innovations, LLC
168 S. Industrial Drive,
Saline, MI 48176

Contact Information:
Kay Fuller, RAC
President & Principal Regulatory & Clinical Research Consultant
Medical Device Regulatory Solutions, LLC
734-846-7852

2. DEVICE INFORMATION

Device Name: VERABAND™

Proprietary Name: VERABAND™

Common Name: Movement/Sleep Assessment Device (actigraphy)

Classification Name: Biofeedback Device (Primary)
Measuring Exercise Equipment

Classification Code: LEL / ISD

Regulation Number: 21 CFR §882.5050 (Primary) / 21 CFR 890.5360

3. PREDICATE DEVICE(S)

Arbor Medical Innovation's VERABAND™ is similar to the primary predicate device K132764 cleared for US commercialization on 1/21/2014 and predicate device K080545 cleared for US commercialization on 7/24/2008.

4. DEVICE DESCRIPTION

The VERABAND™ is a compact, wrist-worn battery-operated wearable device intended for collecting a patient's motion data for assessing patient activity. VERABAND™ is intended to acquire and store data while being worn during normal activities and/or during sleep. The device consists of a wearable band with compact housing for battery-powered on-board electronics with an accelerometer. The recorded activity data is timestamped and stored in non-volatile memory for later retrieval. Downloaded VERABAND™ data can be post-processed based on the timestamp and magnitude of acceleration for reporting.

5. INDICATIONS FOR USE

The VERABAND™ is a compact, lightweight, body-worn activity monitoring device designed to document physical movement associated with applications in physiological monitoring. The device is intended to monitor limb or body movements during daily living and sleep for a limited time interval (up to 30-days). The VERABAND™ can be used to assess activity in any instance where quantifiable analysis of physical motion is desired. VERABAND™ is not intended for diagnostic purposes.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The VERABAND™ fundamental technological characteristics are similar to those of the predicate devices as described herein, and as described in the following table:

Parameter	Subject Device K233987 VERABAND™	Primary Predicate K132764 MotionWatch	Secondary Predicate K080545 ActiTrainer
Intended Use	The VERABAND™ is a compact, lightweight, body-worn activity monitoring device designed to document physical movement associated with applications in physiological monitoring. The device is intended to monitor limb or body movements during daily living and sleep for a limited time interval (up to 30-days). The VERABAND™ can be used to assess activity in any instance where quantifiable analysis of physical motion is desired. VERABAND™ is not intended for diagnostic purposes.	The MotionWatch and PRO-Diary are compact, lightweight, body-worn activity monitoring devices that may be used to document physical movement associated with applications in physiological monitoring. The devices are intended to monitor limb or body movements during daily living and sleep. The MotionWatch and PRO-Diary can be used to assess activity in any instance where quantifiable analysis of physical motion is desired. Additionally, the PRO-Diary has a built-in score pad that allows the wearer to subjectively assign and enter responses to pre-programmed questions. The score pad can be used as a substitute or in addition to the traditional written patient diary in conjunction with activity monitoring.	The ActiTrainer 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 ActiTrainer can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.
Device General Description	Compact, wearable, battery operated physical activity data recorder	Compact, wearable, battery operated physical activity data recorder with integrated score pad.	Wearable, battery operated physical activity data recorder
Size and Visual Appearance and Physical description of recorder	Plastic molded wrist style band -maximum 36mm x 20mm x 10mm	Plastic molded wristwatch style casing with detachable band. Size 36 x 28.2 x 9.4 (excluding band)	Wrist band (chest strap option) 8.5cm x3.4cm x1.6 cm
Weight in gms	5 grams, Maximum	9.1 grams	51 grams
Casing Materials	Medical Grade Polycarbonate, biocompatible material	ABS blend	Polycarbonate
Wrist band Materials	Thermoplastic elastomer (TPE), biocompatible material		Nylon & Velcro® (wrist band)
Power Source	Silver-Oxide battery (coin cell)	3.0 volt coin cell battery type CR2032 (1 each, user-replaceable	Lithium-Ion battery Rechargeable via USB
Battery Life	90 days, pre-wear; Sufficient battery life for the post-use return	6 months	N/A-rechargeable
Accelerator Type	Microelectromechanical system (MEMS)-based integrated circuit -3 axis	Microelectromechanical system (MEMS)- based integrated circuit -3 axis	Microelectromechanical system (MEMS)-based integrated circuit – 2 axis
Activity Channels (# of Axis of Orientation)	3	1, 2 or 3	2
Accelerometer Dynamic Range	+/- 2 g	+/- 8g	+/- 5g
Accelerometer Sensitivity	1.0 milli-g (±3%) per Least Significant Bit	12 Bits (A/D Conversion)	4 milli-g Least Significant Bit
Accelerometer Sampling Rate	1.6 Hz down sampled to 1 Hz	50 Hz (Raw Sampling Rate)	30 Hz, Analog method
Firmware	Embedded C	Not Known	Embedded C
Memory	4 MB	512kBytes	1024 kB
Recording time	28 days	182 Days @ 60s epoch	14 days
Water Resistance (Ingress Protection)	IP57	IPX7	IP21 (condensation)
Sterility	None Required	None Required	None Required
Biocompatibility (Wrist Band Materials)	Biocompatible: skin contact (intact skin), prolonged > 24hrs to ≤30 days per ANSI AAMI ISO 10993-5:2009/(R)2014, ISO 10993-10 4th Ed. 2021-11 and ISO 10993-23 1st Ed.2021-01	Standard nylon wrist band.in contact with intact skin surface.	Nylon & Velcro® (wrist band)
Human Factors	Worn on wrist like a wristwatch; No user interaction is required	Worn on wrist like a wristwatch; No user interaction is required	Worn on wrist (optional chest strap); Some user interaction is required
Storage Temp	-20 to 60°C @ 0-93%RH	-25°C to 70°C	-10°C to 50°C
Operating Temp	-20°C to 40°C @ 0-93%RH	5°C to 40°C	0°C to 40°C

7. NON-CLINICAL TESTING SUMMARY

Non-clinical testing was performed on VERABAND™ to validate performance and support a SE determination to the predicate. The following design control, risk management and quality assurance methodologies were utilized to develop VERBAND™:

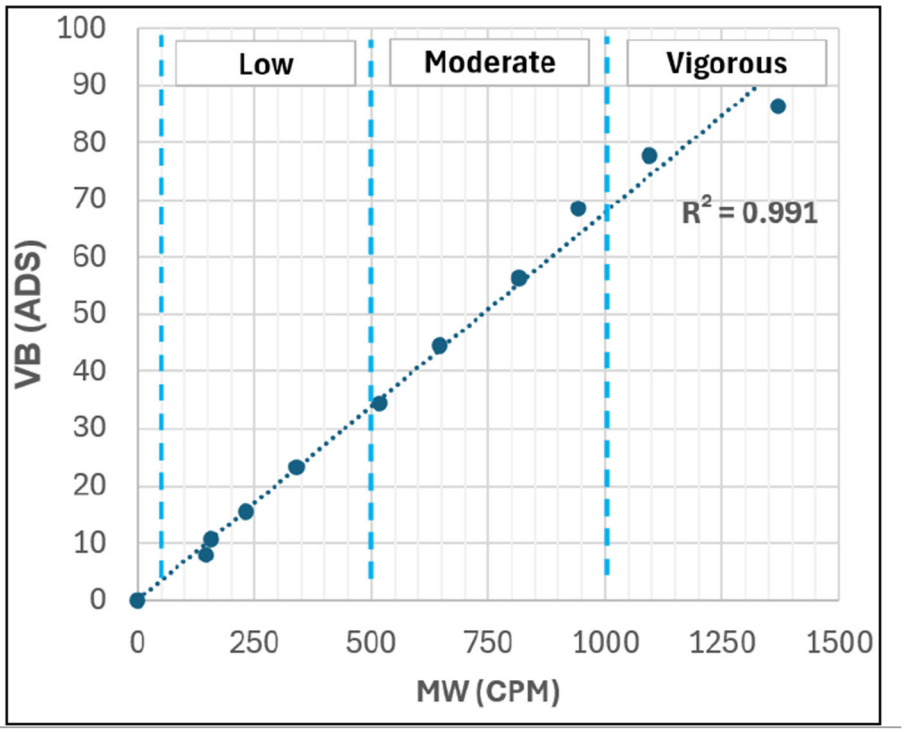
- Risk Analysis
- Requirements Review
- Design Reviews
- Unit Level Testing (Verification)
- Electrical/EMC Safety & V&V Testing
- Performance Testing (Validation)
- Usability & Simulated Use Testing (Validation)
- System compatibility with software for data download/collection/reporting

VERABAND™ Non-Clinical Testing Summary Table

Test	Test Method Summary	Pass/ Fail Criteria	Results
Accelerometer Accuracy and Precision	Using a static and dynamic testing, a range of accelerations are applied to the device.	The accelerometer of the device shall meet the full range accuracy requirement. The accelerometer of the device shall meet the static calibration point accuracy requirement. The accelerometer shall meet the repeatability and reproducibility requirement.	Pass
Activation trigger	Devices are packaged and opened in different light level environments and activation of the device evaluated.	The device shall activate at the required light level. The device shall meet the requirement to not activate while in the packaging.	Pass
Device donning/doffing,	The device band is stretched to simulate donning and doffing multiple times a day and evaluated for damage,	The device shall be able to survive the required donning and doffing.	Pass
Device band separation and band elongation forces	1. The device band is stretched to a specified elongation and the force is evaluated. 2. The band is stretched to failure.	The device shall meet the force requirements for 1. elongation and 2. separation.	Pass
Battery life for duration of use	1. Measure PCB Power Consumption at worst-case temperatures and calculate battery capacity. 2. Measure battery consumption of devices. 3. Evaluate function after different time storage periods	The device shall meet the battery life requirements for Expected Device Life.	Pass
User cleaning	The device is repeatably cleaned per the IFU and evaluated for function.	The device shall maintain function after a required minimum number of cleanings.	Pass
Device Sampling Rate and Full-Scale Dynamic Range	Human accelerometer data is statistically analyzed to confirm the sampling rate and dynamic full-scale range is acceptable for the intended use.	The device shall have a sampling rate and full-scale dynamic range that meets the requirements.	Pass
Device Frequency Response	Simulated accelerations are applied to the device and a predicate over a range of frequencies.	The device shall be within the requirement of the predicate's bandwidth	Pass
VERABAND™ intended use	Simulated users wearing the device perform activities at different intensities of motion and wear compliance times. The data is downloaded and analyzed.	The device shall meet repeatability and reproducibility requirements for activity levels.	Pass
VERABAND™ Report Generation Comparison	Generate simulated motions on VERABAND™ and predicate device. Perform data analysis and compare report outputs.	The device output metrics shall meet the predicate comparison requirements.	Pass
Usability	Users shall wear the device for a fixed time period and respond to a usability survey and the survey results are analyzed.	The device shall meet the related usability requirement survey scores.	Pass
Packaging Testing	Packaging transportation simulation testing per ASTM D4169-22.	Device shall maintain function per requirements after shipping.	Pass
EMC	EMC Testing per IEC 60601-1-2.	The device shall meet the related EMC requirements.	Pass
Electrical Basic Safety	Testing per IEC 60601- and IEC 60601-1-11.	The device shall meet the related electrical basic safety requirements.	Pass
Biocompatibility Testing	Testing per ISO 109993-1.	The device shall meet the related biocompatibility requirements.	Pass
Firmware Verification and Validation Testing	Firmware developed and tested per IEC 62304.	The device shall meet the related Firmware requirements.	Pass
Software Verification and Validation Testing	Software developed and tested per IEC 62304.	The device shall meet the related Software requirements.	Pass

Figure 1, below, provides a graphical summary of the performance output metrics for the subject device and the predicate.

Figure 1. Graphical Summary of VB vs. MW Output Metrics



Basic level software documentation per FDA Guidance *"Content of Premarket Submissions for Device Software Functions",* issued June 14, 2023 was also included in this premarket notification submission. VERABAND™ was developed in accordance with the company's design control procedures and tested in accordance with the company's verification and validation procedures.

Voluntary Recognized Consensus Standards to which the subject device conforms include:

FR Rec. Number	Standard ID	Standard Title
19-49	IEC 60601-1 Edition 3.2 2020-08 Consolidated Version	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
19-36	IEC 60601-1-2 Edition 4.1 2020-09 Consolidated Version	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
19-38	IEC 60601-1-11:2015 + A1:2020	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
5-125	ISO 14971:2019	Medical devices - Applications of risk management to medical devices
2-258	ANSI AAMI ISO 10993-1: 2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
2-245	ANSI AAMI ISO 10993-5:2009/(R)2014	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2-296	ISO 10993-10 4th Ed. 2021-11	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
2-291	ISO 10993-23 1st Ed.2021-01	Biological evaluation of medical devices - Part 23: Tests for irritation
13-79	ANSI AAMI IEC 62304:2006/A1:2016	Medical device software - Software life cycle processes [Including Amendment 1 (2016)]
14-576	ASTM D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems
5-134	ISO 15223-1 4th Ed. 2021-07	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

All predefined acceptance criteria for the engineering (non-clinical) performance testing were met. The results from the non-clinical testing performed on VERABAND™ produced results consistently according to its predefined user needs and intended use.

8. CLINICAL TESTING SUMMARY

The VERABAND™ did not require clinical studies to support substantial equivalence to the primary predicate device.

The VERABAND™ non-clinical and clinical usability results demonstrate that the VERABAND™ clinical user needs and intended use requirements were fulfilled and all predetermined acceptance criteria were met.

9. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

The subject device and the primary predicate device are substantially equivalent, with respect to intended use, instructions for use, design features, technological characteristics, manufacturing methods, performance criteria, special controls, and safety and effectiveness. The subject device is substantially equivalent to the primary predicate device (K132764) noted herein.

10. CONCLUSION

The non-clinical and clinical usability results contained herein, demonstrates that VERABAND™ performs according to its intended use. Arbor Medical Innovations considers the VERABAND™ (subject device) to be substantially equivalent to the legally marketed primary predicate device noted herein, and is safe and effective for its labeled intended use.