November 27, 2023

SOMNOmedics GmbH
% Cherita James
Regulatory Consultant
M Squared Associates/ a PPG Company
127 West 30th St Floor 9
New York, New York 10001

Re: K231104
Trade/Device Name: ABPMpro
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH, DXN
Dated: October 19, 2023
Received: October 19, 2023

Dear Cherita James:

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,

Stephen C. Browning -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular 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)*
K231104

Device Name
ABPMpro

Indications for Use *(Describe)*
ABPMpro Ambulatory Blood Pressure Recorder is a Non-Invasive oscillometric and ECG device intended to acquire Ambulatory non-invasive Blood Pressure signals and 3 Channel ECG signals from the upper body surfaces. Cardiac rhythm is acquired via 3 Channel ECG signals. Additional physiological signals like plethysmogram, body position and activity are also measured. The Recorder is intended for adults and children who are over the age of 12 years.
ABPMpro Software allows transfer of Blood Pressure-, ECG- and data from additional signals from the Recorder to a Windows-based PC-based computer program via USB cable for the purpose of creating reports and printouts. The Software does not perform diagnostics. Physicians carry out diagnostics evaluations of this data. The system is only for measurement, recording and display. It makes no diagnosis."

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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K231104

510(K) SUMMARY

The following information is provided as required by 21 CFR § 807.87 for low impedance cream lic2® 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence determination is based.

Sponsor: SOMNOmedics GmbH
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CJames@MSquaredAssociates.com

Submitted Date:, October 19, 2023

Proprietary Name: ABPMpro

Common Name: ambulatory ECG and non-invasive blood pressure monitor and recorder

Regulatory Class: II

Regulation: 870.2800 Recorder, Magnetic Tape, Medical; 870.1130 System, Measurement, Blood-Pressure, Non-Invasive

Panel: Cardiovascular

Product Codes: DSH, DXN

Predicate Device: Primary- Vasomedical-Biox, K092785

Reference- SOMNOscreen plus , K201054

Device Description: The ABPMpro is a portable device for recording physiological signals. The ABPMpro is used as a long-term blood pressure as well as a long-term ECG device.

The ABPMpro is a portable device worn on the upper arm by means of a cuff and used as an oscillometric 24h ambulatory blood pressure recorder.

The ABPMpro consists of the following hardware:

- ABPMpro recorder with integrated accelerometer and position sensor;
- Brachial blood pressure cuff (3 sizes available)
- Optional: 3-channel ECG sensor
- Optional: Plethysmogram-sensor (LED)

Following the completion of the patient recording session, the device, cuff and electrodes are removed from the patient. The ABPMPro is connected to the PC using the USB cable. With the

downloaded ABPMpro Analyzer Software open on the PC, the user can download the recorded data. The user can select the patient data and begin analysis.

The device is intended for prescription use.

Indications for Use: ABPMpro Ambulatory Blood Pressure Recorder is a Non-Invasive oscillometric and ECG device intended to acquire Ambulatory non-invasive Blood Pressure signals and 3 Channel ECG signals from the upper body surfaces. Cardiac rhythm is acquired via 3 Channel ECG signals. Additional physiological signals like plethysmogram, body position and activity are also measured. The Recorder is intended for adults and children who are over the age of 12 years.
ABPMpro Software allows transfer of Blood Pressure-, ECG- and data from additional signals from the Recorder to a Windows-based PC-based computer program via USB cable for the purpose of creating reports and printouts. The Software does not perform diagnostics. Physicians carry out diagnostics evaluations of this data. The system is only for measurement, recording and display. It makes no diagnosis.

Performance: Performance testing was conducted to confirm compliance to device specifications. All functions were verified to operate as designed. Signal recorded by the ABPMpro underwent performance testing demonstrating that all signal types being recorded comply with the performance criteria set forth by SOMNOmedics that includes the minimum performance specification recommended by the applicable standards for IEC 80601-2-30, which sets forth the definitive standard for devices intended for use in evaluating automated non-invasive sphygmomanometer, and IEC 60601-2-47 for ambulatory ECG.

Usability validation was performed under actual conditions within a clinical study to assess the effectiveness of implemented risk mitigations and confirm safety of the device when used as intended. No incidents of use-related errors were reported. The device was found to be safe and effective for the intended users, use, and use environments. The ABPMpro is not validated for use in exercise stress testing or strenuous exercise. Under certain circumstances, for instance transport in vehicles can have an impact on the measurement results.

Standards

SOMNOmedics GmbH has demonstrated compliance with the following standards for the

ABPMpro.

Standard
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-11:2015 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
IEC 60601-2-47 Edition 2.0 2012-02 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
IEC 80601-2-30: Edition 2.0 2018-03 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
IEC 62366-1:2015 + COR1:2016 Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]
ISO 14971:2007 Medical devices - Application of risk management to medical devices
IEC 62304:2006 + A1:2015 Medical device software - Software life cycle processes [Including Amendment 1 (2016)]
ISO 81060-2 Third edition 2018-11 Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type
ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization

Software validation and cybersecurity assessment for Tier 2 risk level are provided to support the substantial equivalence of the subject device to the predicates.

Clinical Testing: SOMNOmedics GmbH sponsored an open, prospective, clinical validation study to evaluate the accuracy of the APBMpro oscillometric, upper arm device for ambulatory blood pressure (BP) measurement in general population according to the AAMI/ESH/ISO and FDA recognized Universal Standard (ISO 81060-2:2018) both at rest (primary objective) and under dynamic exercise (secondary objective). The clinical investigation received Ethics Committee approval and was conducted in accordance with good clinical practice (GCP) as described in 21 CFR 812.28(a)(1).

Patient population

General validation study:

N=90 age between 12-76, Mean age 39.7 ± 15.1, male 47 (52%), female 43 (48%)

Ambulatory validation study:

N=36 age between 22-65, mean age 40.9 ± 11.0, male 20 (56%), female 16 (44%)

From Publication:

Reference blood pressure

A calibrated (accuracy according to the test protocol for Boso Nova S, Jungingen, Germany is ± 1 mmHg), standard aneroid sphygmomanometer, was used for simultaneous auscultatory reference BP measurements by two observers, using a dual-head teaching stethoscope (Prestige Medical, Northridge, USA). Four different cuff sizes (14–21, 22–32, 33–41, >41 cm) were selected to meet the requirements of the AAMI/ESH/ISO universal standard.

Procedure

The 'same arm sequential method' described in the universal standard was used.

This study showed that the ABPMpro fulfils the accuracy criteria of the ISO 81060-2:2018, both in the general validation as well as in the ambulatory validation study. Thus, the device is recommended for clinical use in adolescents and adults.

Substantial Equivalence Comparison

Features / Technical Information	ABPMpro	Vasomedical-Biox Primary predicate	SOMNOscreen plus Reference predicate	Substantial Equivalence
Product Code	**DXN, DSH**	**DSH, DXN**	**MNR, OLV**	
K-Number	**Not yet assigned.**	**K092785**	**K201054**	
Indications for Use:	ABPMpro Ambulatory Blood Pressure Recorder is a Non-Invasive oscillometric and ECG device intended to acquire Ambulatory non-invasive Blood Pressure signals and 3 Channel ECG signals from the upper body surfaces. Cardiac rhythm is acquired via 3 Channel ECG signals. Additional physiological signals like plethysmogram, body position and activity are also measured. The Recorder is intended for adults and children who are over the age of 12 years. ABPMpro Software allows transfer of Blood Pressure-, ECG- and data from additional signals from the Recorder to a Windows based PC-based computer program via USB cable for the purpose of creating reports and printouts. The Software does not perform diagnostics. Physicians carry out diagnostics evaluations of this data. The system is only for measurement, recording and display. It makes no diagnosis.	Vaosimedical-Biox Combined Ambulatory ECG and Blood Pressure Recorder is a Non-Invasive oscillometric device intended to acquire Ambulatory 3 Channel ECG signals and non-invasive Blood Pressure signals from the upper body surfaces. Cardiac rhythm is acquired via 3 Channel ECG signals. The Recorders are intended for adults and children who are over the age of six years. Vasomedical-Biox Ambulatory ECG CB Series Analysis System Software allows transfer of ECG and Blood Pressure data from the Recorder to a Windows based PC-based computer program via a removable and large capacity storage card (SD) for the purpose of creating reports and printouts. The Software does not perform diagnostics. Physicians carry out diagnostics evaluations of this data. The system is only for measurement, recording and display. It makes no diagnosis.	The SOMNOscreen® plus is a non-life-supporting portable physiological signal recording device intended to be used for testing adults and children/adolescents suspected of having sleep-related breathing disorders.	The Vaosimedical-Biox Combined is for blood pressure and ECG measurements like the ABPMpro. The additional signals are covered by the reference predicate. The intended patient population is different. For Vaosimedical-Biox Combined the patient population is adults and children who are over the age of six years. For ABPMpro it is from 12 years old. The Vaosimedical-Biox Combined has just little bit more range than the ABPMpro. The signals will be transferred to software for display. No diagnosis will be done by the software. The indications are similar.
Prescription Use	Yes	Yes	Yes	Same
Patient population	>12 yo	> 6 yo	>2 yo	Subject device has a

Features / Technical Information	ABPMpro	Vasomedical-Biox Primary predicate	SOMNOscreen plus Reference predicate	Substantial Equivalence
				more limited age range that has been tested clinically.
Use Environment	Hospital, clinic and home use	Hospital, clinic and home use	Hospital or clinic	Same as primary predicate
Measurement Range B/P Pulse rate	Heart Rate: Measurement range: 28-260bpm Accuracy: 5% BP: Measurement range: 0-300mmHg Accuracy: 1.5%	BP: Measurement range: Systolic: 50 - 260 mmHg Diastolic: 30 - 180 mmHg	Heart rate: 18 to 300 bpm	The measurement range for BP of the primary predicate is covered by the ABPMpro. The pulse rate of the reference device is more than the ABPMpro. However, from a medical perspective the edges will not be reached by a human in this application.
Channels	See table sensor comparison	See table sensor comparison	See table sensor Comparison	See Table Sensor Comparison below
Portable Design	Yes	Yes	Yes	Same
Number of Patients can monitor simultaneously	1	1	1	Same
Data Collection	Yes	Yes	Yes	Same
Report Generation	Optional	Optional	Optional	Same
Capable of Data Transfer for Analysis and Report Generation	Yes	Yes	Yes	Same
Data Analysis (Computer or Computer Assisted)	Optional	Optional	Optional	Same
Data transfer to PC	Via USB cable.	Via flash card	Via flash card	Different but both are common ways to exchange data from a device to the PC.
Power Supply	Rechargeable Li ION battery	AA Alkaline battery	Rechargeable Li ION battery	Same as reference predicate

Features / Technical Information	ABPMpro	Vasomedical-Biox Primary predicate	SOMNOscreen plus Reference predicate	Substantial Equivalence
Operation time per charge	24 hours	24 hours	-	Same as primary predicate

Sensor Comparison

Features/Technical Information	ABPMpro	Vasomedical-Biox Primary predicate	SOMNOscreen plus Reference predicate	Substantial Equivalence
Blood Pressure	Yes	Yes	No	SE to reference predicate.
ECG	Yes, 3 lead	Yes, 3 lead	Yes, 3 lead	SE to primary predicate.
Plethysmography-measurement of pulse rate	Yes, sensor placed beneath upper portion of cuff	No	Yes, sensor within the SpO2 finger clip	SE to reference predicate.
Activity and body position (accelerometer)	Yes	No	Yes	SE to reference predicate. The Activity sensor of the SSCplus is a separate sensor applied to the wrist, while the ABPMpro sensor is located on the left upper chest.

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Conclusion: The subject and predicate devices are all intended to measure, record and display physiological signals. The results of the performance testing for the ABPMpro, as well as the substantial equivalence comparison to the predicate devices, are adequate to support a conclusion for the safety and effectiveness of the device. There is no relevant difference in the indications for use or the intended use of the subject device and the predicate device. The subject device has the same principles of operation and technical characteristics as the previously cleared primary and reference predicates. The subject device fulfils the requirements according to IEC 80601-2-30, which sets forth the definitive standard for devices intended for use in evaluating automated non-invasive sphygmomanometer, IEC 60601-2-47 for ambulatory ECG and IEC 60601-1-11 for home use. Patient contacting components have been evaluated for biocompatibility.

The differences do not raise new issues regarding safety or effectiveness.
The ABPMpro could be seen as substantial equivalent to the predicate device.