June 1, 2023

BrainMatterZ, LLC
Kevin Wilson
Chief Commercialization Officer
19830 Fm 1093
Richmond, Texas 77407

Re: K223676
Trade/Device Name: SomniCheck
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological Signal Amplifier
Regulatory Class: Class II
Product Code: GWL
Dated: March 3, 2023
Received: March 3, 2023

Dear Kevin Wilson:

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

Patrick Antkowiak
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K223676

Device Name
SomniCheck

Indications for Use *(Describe)*
SomniCheck is a prescription-use, single use physiological data recorder intended to amplify, digitize, and record data from multiple physiological channels for subsequent transfer to polysomnography systems. The device measures the following signals:

- EEG (4-channel),
- PPG (by Maxim),
- Temperature,
- 3-axis accelerometer,
- Gyroscope (position), and
- Audio/ sound for snoring.

It is intended for use on adult patients (18 and older) and can be used in a hospital, clinic, or home.

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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K223676
Traditional 510(k) Summary

This 510(k) summary was prepared on 3/21/2023 to provide an understanding of the basis for the determination for a determination of substantial equivalence in accordance with the requirements 21 CFR 807.92.

Submitter Information

(a)(1) BrainMatterZ, LLC, 19830 FM 1093, Richmond, TX 77407; contact Mr. Kevin Wilson (phone (469)831-1161, email kwilson@brainmatterz.health). This summary was prepared 5/31/2023.

Subject Device

(a)(2) Device Trade Name: SomniCheck
Common Name: Physiological signal amplifier
Classification Name: Amplifier, Physiological Signal
Regulation Number: 882.1835
Product Code: GWL

Predicate Device

(a)(3) Primary Predicate Device: Sandman SD20 Amplifier (**K040113**, Product Code GWL)
Secondary Predicate Device: NomadAir PMU810 (**K220631**, Product Code GWL)

Device Description

(a)(4) SomniCheck is an integrated single-use disposable physiological data recorder intended to amplify, digitize, and record data from multiple physiological channels for subsequent transfer to polysomnography systems for neurophysiology or sleep disorder studies. It is intended for adult use and can be used in a hospital, clinic, or patient home. The associated software There is proprietary software that is currently under development, but the subject device's signal recording capabilities have been validated using the Natus Sleepworks **K090277** via bench testing. The proprietary sleep software will be submitted in a future 510(k) Submission.

The device is affixed to the forehead of the patient and designed for continuous wear (e.g. during sleep) for up to approximately 10 hours. Once activated, the device records data for the duration of the wear period. After the wear period, the device is removed and may be thrown away. The device measures the following signals:

- EEG (4-channel),
- PPG (by Maxim®),
- Temperature,
- 3-axis accelerometer,
- Gyroscope (position), and
- Audio/ sound for snoring.

Intended Use

(a)(5) SomniCheck is a single use physiological data recorder intended to amplify, digitize, and record data from multiple physiological channels for subsequent transfer to polysomnography systems for neurophysiology or sleep disorder studies. It is intended for adult use (18 years and older) and can be used in a hospital, clinic, or home.

The subject device has the same intended use as the predicate device.

(a)(6) The subject device's technological characteristics are different than those of the predicate devices. However, performance testing adequately accounts for those differences. A comparison of the technological characteristics is available in Appendix A of this Summary.

(b)(1) Non-clinical bench performance tests included System Requirements Verification, Electromagnetic Compatibility (EMC) Verification, and Device Firmware Verification, including applicable clauses from the following standards:

- IEC 60601-1:2020 - Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1-2:2014+A1:2020 - Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
- CISPR 11:2015+A1:2016+A2:2019 - Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
- IEC 60601-1-6:2010+A1:2015 – Medical Electrical Equipment – Part 1-6: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Usability
- 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 60086-4:2019 - Primary batteries - Part 4: Safety of lithium batteries
- IEC 61000-4-2:2008 - Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
- IEC 61000-4-3:2010 - Electromagnetic compatibility (EMC) - Part 4-3 : Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
- IEC 61000-4-8:2009 - Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
- IEC 62304:2006+A1:2015 - Medical device software - Software life cycle processes
- ISO 14971:2019+A11:2021 - Medical Devices -- Application Of Risk Management To Medical Devices
- ISO 13485:2016+A11:2021 - Medical Devices - Quality Management Systems - Requirements For Regulatory Purposes
- Sensor bench testing

(b)(2) Clinical performance testing is not applicable to the device type.

(b)(3) The performance testing demonstrates that the device is as safe, as effective, and performs as well as the legally marketed predicate devices identified in paragraph (a)(3) of this section and therefore substantially equivalent.

Appendix A – Substantial Equivalence Comparison

Aspect	Proposed Device **K223676**	Primary Predicate Device **K040113**	Secondary Predicate Device **K220631**	Comment
Product Name	SomniCheck	Sandman SD20 Amplifier	NomadAir PMU810	**N/A** (differences do not impact safety or efficacy)
Manufacturer	BrainMatterZ, LLC	EB Neuro, S.p.A.	Neurotronics, Inc.	**N/A** (differences do not impact safety or efficacy)
Product Code	**GWL** (21 CFR 882.1835)	**GWL** (21 CFR 882.1835)	**GWL** (21 CFR 882.1835), MNR, DQA	**Same** as Predicates
Device Class	II	II	II	**Same** as Predicates and Reference
Prescribe/OTC	Prescription Only	Prescription Only	Prescription Only	**Same** as Predicates and Reference
Intended Use	SomniCheck is a physiological data recorder intended to amplify, digitize, and record data from multiple physiological channels for subsequent transfer to polysomnography systems for neurophysiology or sleep disorder studies.	Sandman is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations.	Intended to record physiological signals acquired from a patient for archival in a sleep study. Data may be analyzed on dedicated polysomnography software running on a personal computer by a qualified sleep clinician to aid in the diagnosis of sleep-disordered breathing (SDB).	**Same** intended use
Indications for Use	SomniCheck is a prescription-use, single use physiological data recorder intended to amplify, digitize, and record data from multiple physiological channels for subsequent transfer to polysomnography systems. The device measures the following signals: • EEG (4-channel), • PPG (by Maxim),	The SD20 Amplifier is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations.	The NomadAir PMU810 is intended to record physiological signals acquired from a patient for archival in a sleep study. Data may be analyzed on dedicated polysomnography software running on a personal computer by a qualified sleep clinician to aid in the diagnosis of sleep-disordered breathing (SDB). The NomadAir PMU810 is	**Similar;** differences do not introduce a new intended use

Aspect	Proposed Device **K223676**	Primary Predicate Device **K040113**	Secondary Predicate Device **K220631**	Comment
	• Temperature, • 3-axis accelerometer, • Gyroscope (position), and • Audio/ sound for snoring. It is intended for use on adult patients (18 and older) and can be used in a hospital, clinic, or home.		intended for use within a hospital, laboratory, clinic, nursing home, or patient's home. The NomadAir PMU810 is intended for use on adults only under the direction of a physician or qualified sleep technician. The NomadAir PMU810, or any accessory, does not include or trigger alarms, and is not intended to be used alone as, or a critical component of, *an alarm or alarm system; *an apnea monitor or apnea monitoring system; or *a life monitor or life monitoring system.	
Target Population	Adults	[not publicly specified]	Adults	**Adults; Same** as Secondary Predicate
Environment of Use	Hospital, clinic, or patient home	[not specified]	Hospital, clinic, patient home, laboratory, or nursing home	**Same** as Secondary Predicate
Reuse/Single Use	Single use	Reusable	Reusable	**Different**; this difference does not raise different questions of safety and effectiveness; the device measures the same signals and functions in the same manner for patients
Sold Sterile or Non-Sterile	Provided clean, but not sterile	Provided clean, but not sterile	Provided clean, but not sterile	**Same** as Predicates

Aspect	Proposed Device **K223676**	Primary Predicate Device **K040113**	Secondary Predicate Device **K220631**	Comment
Functions	Amplification, Digitization, Storage, Transmission	Amplification, Digitization, Transmission	Amplification, Digitization, Storage, Transmission	**Same** as Predicates
Sensors	The device measures the following signals: • EEG (4-channel), • PPG (by Maxim), • Temperature, • 3-axis accelerometer, • Gyroscope (position), and • Audio/ sound for snoring.	19-channel cutaneous electroencephalograph (EEG), PPG (Nellcor), temperature sensor input, position sensor input, pressure sensor input	4-channel cutaneous EEG, PPG, temperature sensor input, position /acceleration, pressure	**Similar to predicates;** differences do not raise different questions of safety and effectiveness
Power	Internal battery	External IEC 601-1 mains adapter	Internal battery	**Same** as secondary predicate
Wireless connectivity	BLE	none (wired network only)	BLE LTE	**Same** as secondary predicate
Form factor	forehead-wearable patch (adhesive)	head-wearable box (strap) amplifier box	wearable box (strap)	**Similar** to predicates