SOMNOmedics GmbH
Dr. Stefanie Wolski
Regulatory Affairs Am
Sonnenstuhl 63
Randersacker, 97236
Germany

Re: K201054
Trade/Device Name: SOMNOscreen plus
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLV, MNR
Dated: May 13, 2020
Received: May 14, 2020

Dear Dr. Stefanie Wolski:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201054

Device Name
SOMNOscreen plus

Indications for Use *(Describe)*
The SOMNOscreen® plus is a non-life-supporting portable physiological signal recording device intended to be used for testing adults and children (age 2 to 12 years)/adolescents (age 12 and above) suspected of having sleep-related breathing disorders.

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.

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K201054 Traditional 510(k) Summary

The following information is provided as outlined in 21 CFR 807.92 to provide an understanding of the basis for a determination of substantial equivalence.

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Date: August 11, 2020

Subject Device

Trade Name SOMNOscreen® Plus

Classification Class II

Regulation Number & Name Electroencephalograph 21 CFR 882.1400 Neurology

Review Panel Neurology

Identification An electroencephalograph is a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head.

Product Code OLV; Standard Polysomnograph with Electroencephalograph

Definition Acquire, display, store, and archive electroencephalographic signals from the brain and

other signals (such as electromyography, respiratory and/or oximetry signals) for sleep recordings. May also be used to allow on-screen review, user-controlled annotation and user-controlled marking of data.

Secondary Product Code MNR; Ventilatory Effort Recorder (Class II, Breathing frequency monitor, 21 CFR 868.2375)

Identification. A breathing (ventilatory) frequency monitor is a device intended to measure or monitor a patient's respiratory rate. The device may provide an audible or visible alarm when the respiratory rate, averaged over time, is outside operator settable alarm limits. This device does not include the apnea monitor classified in 21 CFR 868.2377.

Predicate Devices

	K040595 Alice® 5 System	**K071556** SOMNOscreen $_{EEG10-20}$	**K060708** SOMNOmedics SOMNOscreen
Product Code(s)	OLZ, OLV	MNR	MNR
Intended Use	Record, display, and print physiological information to clinicians/ physicians. These parameters are presented graphically on a computer screen for diagnostic review, similar in application to the use of a traditional paper-based polygraph recorder. The device will be used in hospitals, institutions, sleep centers or clinics, or other test environments where adults or infant patients require the documentation of various sleep or other physiological disorders. The device does not provide alarms and is not intended for use as an automated apnea	Used for testing adult patients suspected of having sleep-related breathing disorders.	The SOMNOscreen is indicated for use in the recording, displaying, monitoring, printing, and storage of biophysical parameters for the purpose of assisting in the diagnosis of Neurological and Sleep Disorders.

	K040595 Alice® 5 System	**K071556** SOMNOscreen $_{EEG10-20}$	**K060708** SOMNOmedics SOMNOscreen
	monitor.		

Intended Use: The SOMNOscreen® plus is indicated for use in the recording, displaying, monitoring, printing, and storage of biophysical parameters for the purpose of assisting in the diagnosis of Neurological and Sleep Disorders. The device is a non-life-supporting physiological signal recording device intended to be used for studies testing adults and children/adolescents suspected of having sleep-related breathing disorders.

This device is NOT designed to be used in a Life Support situation.

This device is not designed for use on patients with cardiac pacemakers.

Device Description: The SOMNOscreen® plus is a modular system with the following components available.: Thermistor, Nasal Canula, Effort belts and RIP belts with respective sensor, SpO2-Sensor, Microphone, Headbox (EXG Channels), external body position sensor, shoulder belts, activity sensor, EMG-PLM sensor, pressure sensor, ECG sensor, gold cup electrodes and LoFlo CO2-module (optional). The SOMNOscreen® plus device provides 13 AC channels (10 Referential and 3 Differential), 11 Respiratory and AUX Channels, and 8 Internal Channels.

The SOMNOscreen plus is available in 4 different configurations.

- Cardio-RESP
- Home Sleep
- PSG
- EEG 32

The purpose of this 510(k) submission is to expand the patient population to include children and adolescents. For the use in pediatric patients the DOMINO software only allows manual (visual) scoring by qualified RPSG. There is no automated analysis or highlighting available for pediatric patients.

Technical Specifications of the SOMNOscreen Plus:

Features/Technical Specifications	
Modular Channels	13 AC channels, 10 Referential and 3 Differential 11 Respiratory and AUX Channels 8 Internal Channels: - SPO2 - Pulse Rate - Plethysmogram - Body Position - Movement - Light - Patient Marker - Thorax/Abdominal Respiratory Effort
DATA PROCESSING	Active Signal Filtering 16 Bit ADC Recording rate individually programmable (4/s to 512/s)
POWER SUPPLY	Rechargeable Li ION battery (4,2 V) with recording time up to 24 hours. Integrated Safety Chip. The battery has an operating life of approximately 500 charging cycles.
EXTERNAL SENSORS	Abdominal Respiratory Effort Activity sensor (3-Axis) for Actigraphy Active sensor EMG for PLM Pressure sensor (-24 to +24 mbar) for: - Nasal-Oral Flow (Cannula) - CPAP-Pressure - CPAP-Flow - CPAP-Snore
	Additional pediatric sensors: - Soft Silicone Finger Sensor for Pulse Oximeter - Nasal cannula - External body position sensor - MUX Adapter (sensor for inductive effort belts) - Inductive effort belts for pediatrics
INTERACTIVE DISPLAY	Signal Check on the Display Programmable Time Setting Keyboard for Menu Control All menu text on the screen in displayed in capital letters. Maximum 32 characters on 2 lines (16 characters per line) and 2 fields (8 characters per field).
MEMORY	High-speed Compact Flash Card with a capacity up to 2 GB
DIMENSIONS AND WEIGHT	140 x 70 x 28 mm 220 g including battery
TEMPERATURE	During operation: 5° C to 40° C Storage: 0° C to 50°C
SpO2-Modul	
O2 Saturation	70 to 99 %
Pulse Rate	18 to 300 Beats per Minute
Wavelength Red:	660 Nanometer
Infrared:	910 Nanometer
SpO2 (± 1 standard	70 – 100% ± 2% for pediatrics when using the Finger Clip Sensor supplied. Sensor data under 70% are not specified
Pulse Rate	18 to 300 Beats per Minute
Wavelength Red:	660 Nanometer
Infrared:	910 Nanometer

Features/Technical Specifications	
Temperature	During operation: 5°C to +50° C Storage: -20°C to +70°C
Humidity	During operation: 10% - 90%. non-condensing Storage: =10% - 95%, non-condensing

Indications for Use: The SOMNOscreen® plus is a non-life-supporting portable physiological signal recording device intended to be used for testing adults and children (age 2 to 12 years)/ adolescents (age 12 and above) suspected of having sleep-related breathing disorders.

Comparison of Technological Characteristics between Subject and Predicate Devices

	SOMNOscreen® plus K201054	**Alice® 5 System Primary predicate K040595**	**SOMNOscreen EEG10-20 Additional Predicate K071556**	**SOMNOscreen Additional Predicate K060708**	**Comments**
Product Code	OLV, MNR	OLZ, OLV	MNR	MNR	
File Number	K201054	K040595	K071556	K060708	
Indications for Use	The SOMNOscreen® plus is a non-life-supporting portable physiological signal recording device intended to be used for testing adults and children (age 2 to 12 years)/ adolescents (age 12 and above) suspected of having sleep-related breathing disorders.	The Alice 5 system is a polysomnography system that is intended to record, display, and print physiological information for clinicians/ physicians. These parameters are presented graphically on a computer screen for diagnostic review, similar in application to the use of a traditional paper-based polygraph recorder.	The SOMNOscreen EEG10-20 is a non-life-supporting portable physiological signal recording device intended to be used for testing adult patients suspected of having sleep-related breathing disorders.	The SOMNOscreen is a non-life-supporting portable physiological signal recording device intended to be used for testing adult patients suspected of having sleep-related breathing disorders.	Similar target patient population and age range as well as environment of use; all are prescription use devices. The primary predicate, Alice 5, provides automatic detection of events whereas the subject device is not intended to do so. For pediatric populations, only manual scoring by trained personnel should be applied, and the environment of use is limited to hospital/ clinic use for pediatric patients.
Intended Use	The SOMNOscreen® plus is indicated for use in the recording, displaying,	The Alice 5 device will be used in hospitals, institutions, sleep center or clinics, or	The SOMNOscreen is indicated for use in the recording, displaying,	The SOMNOscreen is indicated for use in the recording, displaying,	The SOMNOscreen® plus, as well as the predicate devices, is indicated for use in the recording, displaying, monitoring, printing, and storage of biophysical parameters for the purpose of assisting in the diagnosis of

	monitoring, printing, and storage of biophysical parameters for the purpose of assisting in the diagnosis of Neurological and Sleep Disorders. The device is non-life-supporting physiological signal recording devices intended to be used for studies testing adults and children/adolescents suspected of having sleep-related breathing disorders. The subject is NOT designed to be used in a Life Support situation. The subject is not designed for use on patients with cardiac pacemakers.	other test environments where adults or infant patients require the documentation of various sleep or other physiological disorders. This device does not provide alarms and is not intended for use as an automated apnea monitor.	monitoring, printing, and storage of biophysical parameters for the purpose of assisting in the diagnosis of Neurological and Sleep Disorders.	monitoring, printing, and storage of biophysical parameters for the purpose of assisting in the diagnosis of Neurological and Sleep Disorders.	Neurological and Sleep Disorders. The subject and predicate devices are non-life-supporting physiological signal recording devices intended to be used for studies testing adults, children, and adolescents suspected of having sleep-related breathing disorders. The subject and predicate devices are NOT designed to be used in life support situations. The subject and predicate devices are not designed for use on patients with cardiac pacemakers.	
Prescription Use	Yes	Yes	Yes	Yes	Similar	
Channels	See Table Sensor Comparison	The Alice 5 system is a polysomnographic system that is intended to record,	See Table Sensor Comparison	See Table Sensor Comparison	Similar	

		display, and print physiological information for clinicians/physicians. These parameters are presented graphically on a computer screen for diagnostic review, similar in application to the				
Configuration	Waist belt or desktop	use of a traditional paper-based polygraph recorder.	Waist belt or desktop	Waist Belt or desktop		
Portable Design	Yes	The device will be used in hospitals, institutions, sleep center or clinics, or other test environments where adults or infant patients require the documentation of various sleep or other physiological disorders.	Yes	Yes		Similar
Number of Patients can monitor simultaneously	1 per unit	This device does not provide alarms and is not intended for use as an automated apnea monitor.	1 per unit	1 per unit		Similar
Data Collection	Yes	Yes	Yes	Yes		Similar
Report	Optional	See Table Sensor	Optional	Optional		Similar

Generation		Comparison				
Capable of Data Transfer for Analysis and Report Generation	Yes	Waist belt or desktop	Yes	Yes		Similar
Data Analysis (Computer or Computer Assisted)	Optional, supports only manual (visual) scoring for pediatrics by qualified RPSG	Yes	Optional	Optional		SOMNOscreen plus only supports manual scoring for children and adolescents
Comprehensive Report Generation	Optional	1 per unit	Optional	Optional		Similar
Remote Capability to Monitor Lead Quality	Yes	Yes	Yes	Yes		Similar
Electrode Imped. Check	Yes	Optional	No	No		Similar; Electrode impedance can be measured in SOMNOscreen plus and Alice 5.
Calibration Check	Yes	Yes	Yes	Yes		Similar
Selectable Montage Configuration	Yes	Optional	Yes	Yes		Similar
Annotations on Study	Yes	Optional	Yes	Yes		Similar

Study Modes	Polysomnography Recording, Long Term displaying, Retrieval and Replay	Yes	Polysomnography Recording, Long Term displaying, Retrieval and Replay	Polysomnography Recording, Long Term displaying, Retrieval and Replay		Similar
Optional Equipment	Digital Video / Printer	Yes	Digital Video / Printer	Digital Video / Printer		Similar
Radio LAN Capabilities	Yes	Yes	Yes	Yes		Similar

The sensor principle of the sensors for SOMNOscreen plus has not changed compared to the previously cleared SOMNOscreen and SOMNOscreen EEG10-20. Also, the materials for the external sensors have not changed.

Technical Specification Comparison

Features/Technical Information	**SOMNOscreen plus K201054**	**SOMNOscreen EEG10-20 K071556**	**SOMNOscreen K060708**	**Alice® 5 System K040595**	**Discussion/ Comment**
Data processing	Active Signal Filtering Resolution: up to 16 Bit Storage rate: up to 512 Hz	Active Signal Filtering Resolution: up to 16 Bit Storage rate: up to 512 Hz	Active Signal Filtering Resolution: up to 16 Bit Storage rate: up to 512 Hz	Active Signal Filtering Resolution: up to 16 Bit Storage rate: up to 200 Hz	SOMNOscreen plus allows a higher storage rate in order to support an improved signal quality.

Features/Technical Information	**SOMNOscreen plus K201054**	**SOMNOscreen EEG10-20 K071556**	**SOMNOscreen K060708**	**Alice® 5 System K040595**	**Discussion/ Comment**
Power supply	Rechargeable Li ION battery (4,2 V) with recording time up to 24 hours. Integrated Safety Chip. The battery has an operating life of approximately 500 charging cycles.	Rechargeable Li ION battery (4,2 V) with recording time up to 24 hours. Integrated Safety Chip. The battery has an operating life of approximately 500 charging cycles.	Rechargeable Li ION battery (4,2 V) with recording time up to 24 hours. Integrated Safety Chip. The battery has an operating life of approximately 500 charging cycles.	The base station is powered from a single external medical grade power supply unit: Model MW 116 Power Supply - MW116 Input: 100 to 240 VAC, 50/60 Hz 1.0 A Output: 6.3 VDC, 5.0 A - Base Station Input: 6.3 VDC, 5.0 A The headbox receives its power from the base station via a cable.	Different power supply between SOMNOscreen plus and Alice 5. SOMNOscreen's plus main device is battery powered allowing the patient to freely move around.
Interactive display	Signal check on the display; programmable time setting; keyboard for menu control; all menu text on the screen in displayed in capital letters.	Signal check on the display; programmable time setting; keyboard for menu control; all menu text on the screen in displayed in capital letters.	Signal check on the display; programmable time setting; keyboard for menu control; all menu text on the screen in displayed in capital letters.	No internal display available	Alice 5 does not include an internal display. SOMNOscreen plus offers the possibility to start measurements and do a signal check directly on the main-device using the integrated display.

Features/Technical Information	**SOMNOscreen plus K201054**	**SOMNOscreen EEG10-20 K071556**	**SOMNOscreen K060708**	**Alice® 5 System K040595**	**Discussion/ Comment**
Raw data storage	High-speed Compact Flash Card	High-speed Compact Flash Card	High-speed Compact Flash Card	Hard disk	Different storage technologies between SOMNOscreen plus and Alice 5. These different technological characteristics do not raise safety and effectiveness questions.
Dimensions and weight	Main device: Dimensions: 140 L x 70 W x 28 H mm Weight: 220 g Headbox: Dimensions: 75 L x 72 W x 23 H mm Weight: 220 g	Main device: Dimensions: 140 L x 70 W x 28 H mm Weight: 220 g Headbox: Dimensions: 75 L x 72 W x 23 H mm Weight: 220 g	Main device: Dimensions: 140 L x 70 W x 28 H mm Weight: 220 g Headbox: Dimensions: 75 L x 72 W x 23 H mm Weight: 220 g	Main device: Dimensions: 340 L x 110 W x 300 H mm Weight: 4082 g Headbox: Dimensions – 230 L x 100 W x 40 H mm Weight: 1361 g.	Main device and headbox of SOMNOscreen plus are smaller and lighter than the ones from Alice 5 in order to provide a comfortable use of the SOMNOscreen plus system.
Temperature	During operation: 5° C to 40° C Storage: 0° C to 50°C	During operation: 5° C to 40° C Storage: 0° C to 50°C	During operation: 5° C to 40° C Storage: 0° C to 50°C	During operation: 5° C to 35° C Storage: -20° C to 60°C	SOMNOscreen plus comes with a slightly extended temperature range during operation compared to Alice 5. Temperature range for storage is larger for Alice 5 than for SOMNOscreen plus; however, that does not affect the system during operation.

Performance Testing Summary

The SOMNOscreen plus was verified and validated throughout the design process according to pre-specified requirement specifications, relevant performance standards according to the product's intended use to assure product safety, effectiveness, and reliability. Design and verification testing of all requirement specifications defined for the SOMNOscreen plus was conducted and passed.

The SOMNOscreen plus has been evaluated and found to conform to the following electromagnetic compatibility and electrical safety standards:

IEC 60601-1 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 compatibility

Software documentation to support a moderate level of concern is provided.

AASM Fulfillment

Signal recorded by the SOMNOscreen plus 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 American Academy of Sleep Medicine (AASM). Submission provides a detailed analysis of the requirements from AASM manual, a well-established reference to clinicians when using devices to assist in the evaluation of PSG, and its fulfilment of SOMNOscreen plus compared to ALICE 5 System.

Biocompatibility

Many of the accessory components to be used with the SOMNOscreen plus have been previously cleared by FDA. For new components, the biocompatibility has been established according to ISO 10993.

Declarations of Conformity to the following standards is provided in the submission:

Standard	FDA Recognition #
ISO 14971 Medical devices -- Application of risk management to medical devices	5-40
ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes	N/A
ISO 10993-1 Evaluation and testing within a risk management process	2-220
ISO 10993-5 Tests for in vitro cytotoxicity	2-245
ISO 10993-10 Tests for irritation and skin sensitization	2-174
IEC/ANSI 60601-1:2005	19-4
EN 60601-1-2:2015 (IEC 60601-1-2:2014)	19-8
IEC 62366-1 Edition 1.0 2015-02 Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]	5-114

Clinical Data

Clinical data were not relied upon for a determination of substantial equivalence.

Conclusion

SOMNOscreen plus is substantially equivalent to the predicate devices Alice 5 and SOMNOscreen, SOMNOscreen EEG10-20. The performance testing demonstrated that the device met pre-specified requirements. Based on the methods and results, the subject device is substantially equivalent to the predicate device and is safe and effective for its intended use in the expanded patient population.