August 18, 2023

Beacon Biosignals, Inc.
% Delphine Lemoine
Regulatory Affairs Project Manager
17-21 rue Saint-Fiacre
Paris, 75002, France

Re: K223539
Trade/Device Name: Dreem 3S
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLZ, OLV
Dated: July 19, 2023
Received: July 20, 2023

Dear Delphine Lemoine:

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

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)*
K223539

Device Name
Dreem 3S

Indications for Use *(Describe)*

The Dreem 3S is intended for prescription use to measure, record, display, transmit and analyze the electrical activity of the brain to assess sleep and awake in the home or healthcare environment.

The Dreem 3S can also output a hypnogram of sleep scoring by 30-second epoch and summary of sleep metrics derived from this hypnogram.

The Dreem 3S is used for the assessment of sleep on adult individuals (22 to 65 years old). The Dreem 3S allows for the generation of user/predefined reports based on the subject's data.

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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510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

General Information

Submitter: Beacon Biosignals, Inc.
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Contact Person: Delphine Lemoine
Regulatory Affairs project manager
17-21 rue Saint-Fiacre
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France

Date Prepared: 19 July 2023

Device Information

Trade name: Dreem 3S
Common Name: Sleep Assessment System
Regulation: 21 CFR 882.1400, Electroencephalograph
Product code: OLZ, OLV
Device Class: 2
Review Panel: Neurology

Predicate Device

Nox Medical, Nox Sleep System - K192469.

Device Description

The Dreem 3S headband contains microelectronics, within a flexible case made of plastic, foam, and fabric. It includes 6 EEG electrodes and a 3D accelerometer sensor.

The EEG signal is measured by two electrodes in the frontal band (prefrontal position) and two at the back of the head (occipital position), along with one reference electrode and one ground electrode.
The 3D accelerometer is embedded in the top of the headband to ensure accurate measurements of the wearer's head movement during the night. The raw EEG and accelerometer data are transferred to Dreem's servers for further analysis after the night is over.
The device includes a bone-conduction speaker with volume control to provide notifications to the wearer, and a power button circled by a multicolor LED light
The device generates a sleep report that includes a sleep staging for each 30-second epoch during the night. This output is produced using an algorithm that analyzes data from the headband EEG and accelerometer sensors. A raw data file is also available in EDF format.
The algorithm uses raw EEG data and accelerometer data to provide automatic sleep staging according to the AASM classification. The algorithm is implemented with an artificial neural network. Frequency spectrums are computed from raw data and then passed to several neural network layers including recurrent layers and attention layers. The algorithm outputs prediction for several epochs of 30 seconds at the same time, every 30 seconds. The various outputs for a single epoch of 30 seconds are combined to provide robust sleep scoring.

Indication for use

The Dreem 3S is intended for prescription use to measure, record, display, transmit and analyze the electrical activity of the brain to assess sleep in the home or healthcare environment.
The Dreem 3S can also output a hypnogram of sleep scoring by 30-second epoch and summary of sleep metrics derived from this hypnogram.
The Dreem 3S is used for the assessment of sleep on adult individuals (22 to 65 years old). The Dreem 3S allows for the generation of user/predefined reports based on the subject's data.

Technological Characteristics and Comparison

The Dreem 3S is substantially equivalent to the Nox Sleep System (K192469) from Nox Medical based on the technological and performance characteristics as described in the summary table below.

The subject device Dreem 3S and the predicate Nox Sleep System are both for the assessment of sleep and are both used to measure, record, display, transmit and analyze physiological parameters during sleep and wake in the home and healthcare facility. Both subject and predicate devices are used to aid diagnosis of adult patients with disturbed sleep. Both devices allow for the generation of user/predefined reports based on the subject's data. Both the subject and predicate devices may be used in home and healthcare facilities. Both devices are for prescription use only.

It is thus concluded that the intended use of the Dreem 3S is substantially equivalent to the Nox Sleep System.

The comparison table below is provided as a summary of the most relevant characteristics of the Dreem 3S relative to the primary predicate Nox Sleep System.

Technological	Subject Device	Predicate Device	Comparison to

Characteristic			**Predicate Device**
Device Name	Dreem 3S	Nox Sleep System	N/A
Manufacturer	Beacon Biosignals, Inc.	NOX MEDICAL	N/A
510(k) #	K223539	K192469	N/A
Regulation Number	21 CFR 882.1400	21 CFR 882.1400	Same
Class	2	2	Same
Device Classification Name	Automatic Event Detection Software for PSG with EEG	Automatic Event Detection Software For PSG With EEG	Same Like the Predicate Device, the Dreem 3S is composed of a software for automatic analysis and staging of the EEG measurements.
Product Codes	OLZ, OLV	OLZ, KZM	Same regulation and primary product code 882.1400
Portable Design	Yes	Yes	same
Patient Worn Device	Yes	Yes	same
Physical dimensions	Head perimeter 540mm to 620mm. One size fits all. Adjustable with XS, S, M, L spacers.	Nox A1 Recorder: 82x63x21 mm Nox C1 Access Point: 135x149x26 mm	same
Weight	130g	Nox A1 Recorder: 92 g (120 g with battery) Nox C1 Access Point: 264 g	No significant difference
Materials	ABS Soft polyester fabric	Plastic, ABS/Polycarbonate blend	Similar materials of construction.
Method of Connection to Patient	6 dry electrodes for EEG assessment on the headband. 3D-accelerometer for movement/body position assessment. Bone conduction audio system.	Respiratory bands/belts for respiratory effort. Respiratory bands/belts for attaching the device and clip straps to secure the position of the device Plastic tubing and cannula for pressure sensing. Snap-on electrode cables with snap-on disposable electrodes for EMG/EOG. Thermal flow sensors/thermocouple for measuring nasal/oral airflow. Nox A1 EEG 5 Lead Gold Electrode Cable and Nox A1	The Dreem 3S only utilizes EEG electrodes unlike the predicate, which has additional inputs which can be selected by the user if needed. The use of only EEG electrodes does not impact the subject device's performance for the intended use in automatic sleep scoring.

		EEG Head Cable for EEG/EOG. Surface electrode leads for EEG/EOG/EMG. Surface Electrodes for measuring of leg movements. Wrist-worn oximeter and probes for oximetry worn on the finger.	
Data Analysis	Automatic scoring and derived sleep metrics are provided to the health care provider through a specific report, in a pdf file. Manual analysis and marking are available on raw data.	Yes, by use of Noxturnal PSG SW (PC). Automatic results may be manipulated (manual review/verification must be performed prior to diagnosis). Manual analysis. Event marking (scoring). Technician Notes.	Both devices allow the generation of reports with accurate data analysis and provide access to the patient's raw data.
#Channels of data recorded	5 EEG channels from 5 electrodes: Frontal - Occipital Frontal - Occipital Frontal - Frontal	Nox A1 recorder: up to 26 Nox C1 Access Point: up to 16	The subject device has fewer EEG channels than the predicate device.
Operating Time	Up to 24 hours	Up to 8 hours	Subject device has longer battery life.
Sensors	- EEG dry electrodes x6 - Accelerometer	- Nox A1 EEG 5 Lead Gold Electrode Cable - Disposable electrodes for EMG/EOG - Thermal flow sensors / thermocouple - Surface Electrodes for measuring leg movements - Oximeter and probes for oximetry	The Subject Device's sensors are a subset of the Predicate Device's sensors. Also, we note that, while the predicate device does not use dry EEG electrodes, the. Neuronaute (K170138) is an example of a FDA cleared device that does use dry EEG electrodes.
Recording Time	Same as the operating time. Up to 24 hours.	Up to 8 hours	Subject device has longer recording time

Non-Clinical Performance

The Dreem 3S has been evaluated against the following electromagnetic compatibility and electrical safety standards:

- *IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
- *IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests*

- *IEC TR 60601-4-2:2016 Medical electrical equipment – Part 4-2: Guidance and interpretation –Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems*
- *IEC 60601-2-26 Medical electrical equipment -- Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs*

The Dreem 3S is intended to be used in the patient's home and has been evaluated against the following electrical safety and performance standard for home healthcare environment:

- *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*

The Dreem 3S has undergone usability testing to comply with standards *"IEC 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability"* and "IEC 62366-1:2015/Amd1:2020 *Medical devices — Part 1: Application of usability engineering to medical devices – Amendment 1".*

All body contacting components (fabric inside the headband, front and back electrodes, bone conduction, pod) have gone through successful biocompatibility testing according to biocompatibility standards:

- *ISO 10993-1 Fifth Edition 2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
- *ISO 10993-5 Third Edition 2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*
- *ISO 10993-10 Third Edition 2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization*

Clinical Performance

The Dreem 3S performance has been assessed through the following investigations:

Performance compared to lab PSG. A clinical investigation was completed that compared Dreem 3S sleep staging output with a 510(k)-cleared PSG system in a sleep lab setting on patients with disturbed sleep. This study included 38 subjects ranging from 23 to 66 years old with a mean ± standard deviation age of 35.8 ± 11.6 years. Subjects were equally split between male and female, and included individuals self-identified as White, Black African American, Asian, Hispanic and some not identified. A total of 36447 epochs, corresponding to about 303 hours and 43 minutes of sleep were included the study.

Data from this study is summarized in a confusion matrix below in table 2 comparing the performance of the Dreem device with expert-scored sleep stages from a cleared device. Table 3 provides subject-level positive agreement for each stage with bootstrapped confidence interval.

Table 2: Confusion matrix comparing Dreem 3S and consensus of expert-scored PSG for all sleep epochs is summarized as percentages in the table below.

		Consensus from manual staging				
		W	N1	N2	N3	REM
Dreem 3S (Automated analysis)	W	90.7%	14.1%	0.6%	0.1%	1.4%
	N1	4.4%	55.2%	1.8%	0.0%	1.0%
	N2	0.8%	21.8%	83.7%	2.1%	2.2%
	N3	0.2%	0.2%	11.7%	97.8%	0.0%
	REM	3.8%	8.7%	2.2%	0.0%	90.7%
	Unassigned	0.01%	0.0%	0.0%	0.0%	0.0%
	Epoch count	6719	2582	17534	3922	5690

Table 3: Average subject-level positive agreement (PA) per sleep stage of the Dreem 3S compared to the expert-scored PSG with bootstrapped confidence intervals (CI).

Stage	**Dreem 3S Positive Agreement with Bootstrapped CI estimates (2.5%, 97.5%)**
Wake	88.5% (85.1%, 91.3%)
N1	58.0% (52.7%, 63.0%)
N2	83.4% (80.7%, 85.7%)
N3	98.2% (96.73%, 99.3%)
REM	91.57% (86.63%, 95.72%)

EEG data quality. A study was conducted to establish that EEG data quality from Dreem 3S is sufficient for manual review and scoring of data. 96.6% epochs per night of recording were determined to be acceptable for manual scoring and sleep staging by at least two out of three

reviewers qualified to read EEG and/or PSG data. All data recordings reviewed had ≥4 hours of data considered to be scoreable by at least two out three reviewers.

Usability Study. An investigation was completed to assess usability in the home setting and showed that the device could be successfully used and was tolerated by study subjects.

Conclusions

Based on the comparison to the predicate device and performance studies, the Dreem 3S is substantially equivalent to the currently U.S. legally marketed device Nox Sleep System (K192469) and presents no new concerns about safety or effectiveness.