



November 22, 2024

Beacon Biosignals, Inc.  
Alexander Chan  
VP of Analytics and Machine Learning  
22 Boston Wharf Road  
7th Floor, Unit 41  
Boston, Massachusetts 02210

Re: K242094  
Trade/Device Name: Dreem 3S  
Regulation Number: 21 CFR 882.1400  
Regulation Name: Electroencephalograph  
Regulatory Class: Class II  
Product Code: OLZ, OLV  
Dated: October 18, 2024  
Received: October 21, 2024

Dear Alexander Chan:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not

required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jay R. Gupta -S

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

## Indications for Use

Submission Number (if known)

K242094

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.**

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.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*



# 510(k) SUMMARY

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

## SUBMITTER

Applicant	Beacon Biosignals, Inc. 22 Boston Wharf Rd. 7 <sup>th</sup> Floor, Unit 41 Boston, MA 02210
Contact	Alexander Chan VP of Analytics and Machine Learning Email: alex.chan@beacon.bio
Date Prepared	21 June 2024

## DEVICE INFORMATION

### Subject Device

Name of Device	Dreem 3S
Regulation	21 CFR 882.1400
Product Code	OLZ, OLV
Device Class	Class II
Review Panel	Neurology

### Predicate Device

Predicate Manufacturer	Beacon Biosignals, Inc.
Predicate Trade Name	Dreem 3S
Predicate 510(k)	K223539

## 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 previous version of the Dreem 3S (K223539) based on the technological and performance characteristics as described in the summary table below.

The subject device Dreem 3S and the predicate Dreem 3S (K223539) have identical technological characteristics except for the presence of a Predefined Change Control Plan (PCCP) that is a new characteristic of the subject device. The PCCP allows for the update of the algorithmic components of the Dreem 3S device. Both subject and predicate device are 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 the previously cleared version of the Dreem 3S (K223539).**

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

**TABLE 1 : COMPARISON OF TECHNOLOGICAL CHARACTERISTICS**

Technological Characteristic	Subject Device	Predicate Device	Comparison to Predicate Device
Device Name	Dreem 3S	Dreem 3S (K223539)	N/A
Manufacturer	Beacon Biosignals, Inc.	Beacon Biosignals, Inc.	Same
Regulation Number	21 CFR 882.1400	21 CFR 882.1400	Same
Class	2	2	Same

<b>Device Classification Name</b>	Automatic Event Detection Software for PSG with EEG	Automatic Event Detection Software for PSG With EEG	Same
<b>Product Codes</b>	OLZ, OLV	OLZ, OLV	Same
<b>Portable Design</b>	Yes	Yes	Same
<b>Patient Worn Device</b>	Yes	Yes	Same
<b>Physical dimensions</b>	Head perimeter 540mm to 620mm. One size fits all. Adjustable with XS, S, M, L spacers.	Head perimeter 540mm to 620mm. One size fits all. Adjustable with XS, S, M, L spacers.	Same
<b>Weight</b>	130g	130g	Same
<b>Materials</b>	ABS Soft polyester fabric	ABS Soft polyester fabric	Same
<b>Method of Connection to Patient</b>	6 dry electrodes for EEG assessment on the headband. 3D-accelerometer for movement/body position assessment. Bone conduction audio system.	6 dry electrodes for EEG assessment on the headband. 3D-accelerometer for movement/body position assessment. Bone conduction audio system.	Same
<b>Data Analysis</b>	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.	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.	Same
<b>#Channels of data recorded</b>	- 5 EEG channels from 5 electrodes (4 frontal-occipital derivations, 1 frontal-frontal derivation) - 3 Triaxial accelerometer channels	- 5 EEG channels from 5 electrodes (4 frontal-occipital derivations, 1 frontal-frontal derivation) - 3 Triaxial accelerometer channels	Same
<b>Operating Time</b>	Up to 24 hours	Up to 24 hours	Same

<b>Recording Time</b>	Same as the operating time. Up to 24 hours.	Same as the operating time. Up to 24 hours.	Same
<b>Predetermined Change Control Plan</b>	Includes PCCP that allows for the update of the signal preprocessing, machine learning model, and probability postprocessing.	No PCCP	Different - Predicate devices does not include a PCCP

## PERFORMANCE TESTING

No bench testing, animal testing, or clinical testing was performed to support this submission. Because this submission only involves the additional inclusion of the Predetermined Change Control Plan, the performance characteristics of the submitted device are the same as previously reported for the predicate device (K223539).

## PREDETERMINED CHANGE CONTROL PLAN

Dreem 3S includes an authorized Predetermined Change Control Plan (PCCP) that allows for planned updates of the machine learning software device function (ML-DSF) and non-ML algorithmic components to improve sleep staging performance within the existing intended use and indications for use. This PCCP allows for the modification of the algorithmic components of Dreem 3S including the signal preprocessing, machine learning model, or postprocessing to achieve increased sleep staging performance. The three modifications are summarized in the table below.

#	Modification	Description
1	Update of Signal Preprocessing Steps	Dreem 3S's EEG signal preprocessing may be modified for the purposes of improving sleep staging performance within the intended use population by: <ul style="list-style-type: none"> <li>Updating the parameters of the digital signal processing steps (e.g., filtering) applied to the Dreem 3S headband signals before being input to the machine learning model</li> </ul>
2	Update of Machine Learning Model	Dreem 3S's sleep staging neural network may be modified for the purposes of improving sleep staging performance within the intended use population by: <ul style="list-style-type: none"> <li>Retraining with an updated training/tuning dataset</li> <li>Retraining with updated hyper-parameters, loss function, optimizer</li> <li>Retraining with updated model selection criteria</li> <li>Retraining with an updated neural network architecture with limitations on model size and type</li> </ul>
3	Update of Probability Postprocessing	Dreem 3S's probability postprocessing may be modified for the purposes of improving sleep staging performance within the intended use population by: <ul style="list-style-type: none"> <li>Updating the methods by which sleep stages are generated from the model output sleep stage probabilities</li> </ul>

Modifications 1 and 2 above would trigger re-training of the machine learning model, while modification 3 would not trigger re-training of the machine learning model.

The testing of any modification to Dreem 3S within the scope of the PCCP will include comprehensive software verification and validation testing, including repeating unit, integration, and system level tests related to the software components affected by the change. All of these software

verification tests must pass for a modification to be considered valid. In addition, clinical performance validation will also be repeated, and will require that the performance of any modification to Dreem 3S to be non-inferior to the all previously released versions of the Dreem 3S device. Non-inferiority margins were selected based on the level of human variability estimated from comparison of expert scoring from 284 American Academy of Sleep Medicine (AASM) compliant polysomnography recordings.

Recordings that are used for any purpose (e.g., training, tuning, failure analysis, etc.) that might lead to direct or indirect insight regarding the performance of a modified sleep staging algorithm on this recording, other than execution of the clinical performance validation per the methods specified in the PCCP, are excluded from the test dataset. Quality checks will ensure that the test data are sufficiently high quality and representative of the intended use population.

Upon a release of an updated version of Dreem 3S based on this PCCP, communication will be provided to all clinical users of Dreem 3S, informing them that a new version of Dreem 3S is available, with a description of the release and its updated performance.

## **CONCLUSIONS**

The Dreem 3S is substantially equivalent to the previous version of the legally marketed Dreem 3S (K223539) and presents no new concerns about safety or effectiveness.