April 3, 2024

Oxehealth Limited
Joao Jorge, PhD
Sleep Analysis Lead
Magdalen Centre North
Oxford Science Park
Oxford, OX4 4GA
United Kingdom

Re: K233618
Trade/Device Name: Oxevision Sleep Device
Regulation Number: 21 CFR 882.5050
Regulation Name: Biofeedback device
Regulatory Class: Class II
Product Code: LEL
Dated: March 4, 2024
Received: March 4, 2024

Dear Joao Jorge:

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,

FDA 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233618

Device Name

Oxevision Sleep Device

Indications for Use *(Describe)*

The Oxevision Sleep Device is an activity monitor designed and intended for documenting physical movements associated with applications in physiological monitoring. The device's intended use is to analyze subject activity, movement and physiological sign data associated with movement during sleep and to extract information about certain sleep parameters from these movements and physiological sign data.

The device provides a timeline of periods when a bed space is occupied, and periods when a subject is asleep when the bed space is occupied.

The Oxevision Sleep Device is software assessing video footage from a fixed-installation device for use within single occupancy bed spaces within hospitals, general care and secured environments.

The Oxevision Sleep Device is indicated for use on subjects 18 years of age or older.

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.

510(k) Summary

Oxevision Sleep Device
K233618

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

General information

Submitter's Name:	Dr. Joao Jorge
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Contact Person:	Dr. Joao Jorge
Email:	joao.jorge@oxehealth.com
Date Prepared:	4 March 2024

Device Information

Trade name:	Oxevision Sleep Device
Common Name:	Sleep Assessment System
Address of Sponsor:	Oxehealth Limited Magdalen Centre North, Oxford Science Park, Oxford, OX4 4GA UK
Classification Name:	LEL, Biofeedback device, 21 CFR 882.5050
Predicate Device:	Fatigue Science, SBV2™ System - K111514

Indication for Use: The Oxevision Sleep Device is an activity monitor designed and intended for documenting physical movements associated with applications in physiological monitoring. The device's intended use is to analyze subject activity, movement and physiological sign data associated with movement during sleep and to extract information about certain sleep parameters from these movements and physiological sign data.

The device provides a timeline of periods when a bed space is occupied, and periods when a subject is asleep when the bed space is occupied.

The Oxevision Sleep Device is software assessing video footage from a fixed-installation device for use within single occupancy bed spaces within hospitals, general care and secured environments.

The Oxevision Sleep Device is indicated for use on subjects 18 years of age or older.

Device Description: Oxevision Sleep is a software-only medical device (SaMD) that provides non-contact sleep assessment in the inpatient setting based on the analysis of patient movement, activity and physiological sign data derived from video, without the need for contact devices to be attached to the patient or bed.

The device consists of custom-designed software assessing video footage collected using off-the-shelf cameras installed within single occupancy bed spaces within hospitals, general care and secured environments. Proprietary software-controlled algorithms are used to derive patient movement, activity and physiological sign data and then to obtain information on bed occupancy and sleep state from the analysis of this data.

The device software automates recognition of sleep periods, generation of sleep reports, and their presentation in a graphical display for use by a healthcare professional.

Technological Characteristics and Comparison:

The Oxevision Sleep Device is substantially equivalent to the SBV2™ System (K111514) from Fatigue Science Inc. based on the technological and performance characteristics as described in *Table 1*.

The subject device, Oxevision Sleep Device, and the predicate SBV2™ System are both intended for the assessment of sleep and are both used to measure, record, display, transmit and analyze physiological parameters during sleep and wake. Both are intended for documenting physical movements associated with applications in physiological monitoring in patients, and derive sleep measurements from these movements. Both can be used on adult patients. Both provide a timeline of periods when a subject is in bed, and of periods when a subject is asleep for a set time period (e.g. 7 days.) in

reports that can be viewed and exported in electronic format. These similarities led to the conclusion that the Oxevision Sleep Device is substantially equivalent to the SBV2™ System.

Table 1: Comparison between the Oxevision Sleep Device and the previously cleared SBV2 System [K111514] (cleared by FDA under the LEL product code).

	Subject Device	Predicate Device	Equivalence
Trade Name	Oxevision Sleep Device	SBV2	
Reference	K233618	K111514	
Sponsor	Oxehealth Limited	Fatigue Science Inc.	
Intended Use	Sleep Assessment Device	Sleep Assessment Device	
Product Code	LEL	LEL	*Same as the predicate device.*
Intended Use	The Oxevision Sleep Device is an activity monitor designed and intended for documenting physical movements associated with applications in physiological monitoring. The device's intended use is to analyze subject activity, movement and physiological sign data associated with movement during sleep and to extract information about certain sleep parameters from these movements and physiological sign data.	The SBV2 System is an activity monitor designed and intended for documenting physical movements associated with applications in physiological monitoring. The device's intended use is to analyze limb activity associated with movement during sleep and to extract information about certain sleep parameters from these movements. SBV2 can also be used to assess activity in any instance where quantifiable analysis of physical motion is desirable.	*Substantially equivalent to the predicate device.*
Intended Use Population	The Oxevision Sleep Device is indicated for use on subjects 18 years of age or older.	The use of SBV2 is indicated for adults 22 years of age and over.	*Intended use population is substantially equivalent to the predicate device. Differences in age groups have been validated as part of a US-census balanced study cohort.*
Commercial distribution	Prescription use.	Indicated for Over the Counter (OTC) Use. Patient receives data recording unit from a dispensing agent such as a pharmacist.	*Prescription use represents a lower risk posture than OTC.* *Differences to predicate do not introduce any questions of safety or effectiveness.*
Intended use environment	Single occupancy bed spaces within hospitals, general care and secured environments.	Body-worn device providing actigraphy data to a PC processing application/software. For use in any sleeping location.	*No change from reference device.*
Data Collection	Data collection is from an off-the shelf video camera, collecting continuously. The specification of the camera and qualification as suitable for use is controlled by Oxehealth	Data recording unit is attached to patient's limb or torso and worn continuously	*Differences to predicate do not introduce any questions of safety or effectiveness.* *Clinical performance has been validated and found to be as good or better than the predicate.*

	Subject Device	Predicate Device	Equivalence
User Interface	Application developed by the manufacturer, installed on OTS computer or mobile device. Installed by Oxehealth with no other applications in the operating environment.	Application developed by the manufacturer, installed on OTS computer. Installed by the user on a BYOD platform.	*Differences to predicate do not introduce any questions of safety or effectiveness.*
Compatibility with Hardware	Standard, off the shelf computers and mobile devices, specified and installed by Oxehealth, and validated during installation.	SleepAnalyzer application can be used in standard, off-the-shelf computers to retrieve collected data from the data recording unit and generate reports based on collected data.	*Differences to predicate do not introduce any questions of safety or effectiveness.*

Non-Clinical Performance :

Since the device is SaMD using off-the-shelf image acquisition and data processing equipment, no EMC or electrical safety testing has been performed.

Since the device has no patient contacting parts, no biocompatibility or mechanical safety testing has been performed.

Oxehealth have reviewed the FDA's database of recognised consensus standards and has consequently applied the following standards to the development of the device:

- ISO 14971:2019 + A11:2021 - Application of risk management to medical devices
- AAMI BS 34971:2022 - Application of risk management to Artificial Intelligence and Machine Learning Devices
- IEC 62304:2006 + A1:2015 - Software life cycle processes
- IEC 82304-1:2016 - Health software
- IEC 80001-1:2021 - Application of risk management for IT-networks incorporating medical devices — Part 1: Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software
- IEC 81001-5-1:2021 - Health software and health IT systems safety, effectiveness and security — Part 5-1: Security — Activities in the product life cycle
- IEC/TR 80002-1:2009 - Medical device software — Part 1: Guidance on the application of ISO 14971 to medical device software
- IEC 62366-1:2015 +A1:2020 - Application of risk management to medical devices
- ISO 15223-1:2021 - Medical devices — Symbols to be used with information to be supplied by the manufacturer
- ISO 20417:2021 Symbols to be used with information to be supplied by the manufacturer

The firm has also performed penetration and vulnerability testing in line with FDA's guidance on cybersecurity.

Clinical Performance: The clinical performance (validation) testing of the Oxevision Sleep software device was designed to assess the performance of the Oxevision Sleep Device algorithm against reference standards on two tasks:

A. The accuracy of periods of bed occupancy detected using Oxevision Sleep Device algorithms measured against periods of human-labeled bed occupancy is not inferior to 95%;

B. The agreement between Oxevision Sleep Device algorithms in sleep/wake classification measured against polysomnographic reference standard during periods of bed occupancy detected using Oxevision Sleep Device algorithms is not inferior to Agreement = 82%, Positive agreement = 88%, and Negative Agreement = 55%.

These endpoints were selected as they are the stated performance specifications of the predicate device.

The clinical data used to determine the clinical performance of the device was obtained in a sample of 60 individuals (a total of 772.65 hours of data). The demographic characteristics of this sample are shown in *Table 2*.

Table 2: Summary of demographic characteristics for the validation data collected from the 60 adults in the validation sample.

Variable	Value
Age (mean ± std)	48.6 ± 14.5 years
Weight (mean ± std)	76.2 ± 17.7 kg
Height (mean ± std)	168.7 ± 9.7 cm
Body mass index (mean ± std)	26.7 ± 5.6 kg/m^2
Sex Male Female	 30 volunteers 30 volunteers
Fitzpatrick skin type	Ⅰ: 3, Ⅱ: 12, Ⅲ: 21, Ⅳ: 6, Ⅴ: 10, Ⅵ: 8

Reference measurements (physiological signals and video polysomnography data) were collected using an FDA-cleared polysomnography (PSG) device (SOMNOscreen™ plus device, Somnomedics, Germany). Video data was collected concurrently from a standard off-the-shelf camera and hardware installed in two rooms according to the Oxehealth Installation Instructions for use with the Oxevision Sleep Device software.

Reference PSG measurements were assessed and scored (in accordance with the American Academy of Sleep Medicine Manual for the Scoring of Sleep and Associated Events version 2.6 of January 2020) by three trained sleep physiologists, blinded to the video data collected by the standard off-the-shelf camera.

Oxevision video data was reviewed and annotated (to obtain a reference standard) for periods of bed occupancy by two reviewers, blinded to the algorithm development details.

Table 3: Confusion matrix of Oxevision Sleep Device outputs against the reference standards of expert-scored PSG and annotated bed occupancy for all epochs in the validation sample A.

No. epochs			**Reference standard** from expert-scored PSG and annotated bed occupancy			
			In Bed			*Out-of-bed*
			Sleep	*Wake*	*No sleep status*[1]	
Oxevision Sleep	In Bed	*Sleep*	*33,951*	*2,872*	*78*	*0*
		Wake	*2,072*	*11,203*	*2*	*136*
		No sleep status	*1,273*	*169*[2]	*0*	*213*
	Out-of-bed		*0*	*102*	*1*	*25,753*
	State unavailable		*5*	*844*	*0*	*955*

The analysis of pertinent data held by Oxehealth and used for the validation of the algorithm was performed under the following protocols.

The outputs of the Oxevision Sleep Device were evaluated against the reference standard for sleep states obtained from triple-scored PSG data to obtain sleep state statistics; and against the reviewer-annotated bed occupancy states to obtain bed state statistics.

[1] The sleep state reference was constructed using epoch-by-epoch majority vote (see example in Appendix D - PSG reference standard for sleep state). Per protocol for data analysis in *SLP.REG.241: Validation of the Oxevision Sleep device: Protocol for clinical data analysis*, epochs for which no majority label was available, which occurred as sleep physiologists may label epochs as artefact under AASM guidelines, are excluded from the analysis. The number of epochs excluded for this reason will be reported.

[2] This table entry has been amended due to a code print error in the previous version of this document. The previous version read 844 instances. Primary and secondary outcomes had been computed on the correct data, so no amendments were needed.

Table 4: Performance of Oxevision Sleep device algorithms in the validation sample A data. An asterisk (*) denotes secondary outcome measures.

Clinical-related evaluation of Oxevision Sleep Device outputs					
Bed State outputs		**Sleep State outputs**			
*Bed State Unavailable	Accuracy	*Sleep State Unavailable	Overall Agreement	Positive Agreement	Negative Agreement
2.3%	99%	2.8%	90%	94%	80%

Table 5 presents per epoch agreement statistics between the outputs of the Oxevision Sleep Device and the reference standards for bed occupancy state and sleep state.

Table 5: Performance of Oxevision Sleep Device algorithms in validation data collected from the 60 participants.

Clinical-related evaluation of Oxevision Sleep Device outputs			
Bed State outputs	**Sleep State outputs**		
Accuracy	Overall Agreement	Positive Agreement	Negative Agreement
>95%	*>82%*	*>88%*	*>55%*

The results show overall agreement (>82%), positive agreement (>88%) and negative agreement (>55%) between Oxevision Sleep Device outputs and the gold-standard PSG reference. A bed state accuracy of >95% against reviewer annotations was also reported.

Two-sided 95% confidence intervals for the mean of each performance statistic were obtained using a bootstrap resampling approach.

Table 6: Two-sided 95% confidence intervals for the mean of each outcome measure over the 60 study sessions in the evaluation data (including validation samples A and B). Two-sided 95% confidence intervals were obtained based on the 2.5th and 97.5th percentiles of the bootstrap distribution of resamples (10,000 resamples).

95% Confidence intervals for primary outcome measures			
Bed State outputs	**Sleep State outputs**		
Accuracy	Overall Agreement	Positive Agreement	Negative Agreement
(99.0%; 99.7%)	(89.0%; 91.8%)	(92.3%; 95.6%)	(74.3%; 83.5%)

This testing demonstrated device performance was superior to that produced for the predicate device [K111514] in their pre-market submission. All performance endpoints have therefore been met, which substantiate the claim of substantial equivalence to the predicate device.

Conclusions

Based on the comparison to the predicate device and performance characteristics, the Oxevision Sleep Device is substantially equivalent to the currently U.S. legally marketed device Fatigue Science, SBV2™ System (K111514) and presents no new concerns about safety or effectiveness.