

**K233618 Oxevision Sleep Device**Apr 3, 2024  
142 days to decisionK233618 · Product code: **LEL** · Neurology  
Source: <https://www.510kdatabase.net/k233618/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Sleep Assessment (LEL)
Date received	Nov 13, 2023
Decision date	Apr 3, 2024
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Oxehealth Limited</b>
Location	Abingdon, GB
Contact	Joao Jorge
510(k) history	6 submissions · 5 cleared · 2021-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233618/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026