

**K241288 Noxturnal Web**Dec 23, 2024  
230 days to decisionK241288 · Product code: **OLV** · Neurology  
Source: <https://www.510kdatabase.net/k241288/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	May 7, 2024
Decision date	Dec 23, 2024
Days to decision	230 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nox Medical Ehf</b>
Location	Reykjavik, IS
Contact	Kolbrún Ottósdóttir
510(k) history	5 submissions · 5 cleared · 2015-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>RQM+</b>
Contact	Hrishikesh Gadagkar

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241288/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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