

**K252330 DeepRESP**Nov 17, 2025  
115 days to decisionK252330 · Product code: **OLZ** · Neurology  
Source: <https://www.510kdatabase.net/k252330/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Polysomnograph With Electroencephalograph (OLZ)
Date received	Jul 25, 2025
Decision date	Nov 17, 2025
Days to decision	115 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	Elísabet Finnbogadóttir
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/k252330/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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