

K241960 DeepRESPMar 14, 2025
254 days to decisionK241960 · Product code: **OLZ** · Neurology
Source: <https://www.510kdatabase.net/k241960/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Polysomnograph With Electroencephalograph (OLZ)
Date received	Jul 3, 2024
Decision date	Mar 14, 2025
Days to decision	254 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	RQM+
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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