FDA 510(k) Premarket Notification

K252330 DeepRESP

CLEARED

Nov 17, 2025
115 days to decision

K252330 · Product code: **OLZ** · Neurology
Source: https://www.510kdatabase.net/k252330/

SUBMISSION DETAILS

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

Company	**Nox Medical Ehf**
Location	Reykjavik, IS
Contact	Elísabet Finnbogadóttir
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