

**K260585 Noxturnal Web**Mar 20, 2026  
28 days to decisionK260585 · Product code: **OLV** · Neurology  
Source: <https://www.510kdatabase.net/k260585/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	Feb 20, 2026
Decision date	Mar 20, 2026
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

**REGULATORY CONSULTANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260585/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026