

K250851 Hypnos (369054-200)Dec 14, 2025
268 days to decisionK250851 · Product code: **OLZ** · Neurology
Source: <https://www.510kdatabase.net/k250851/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Polysomnograph With Electroencephalograph (OLZ)
Date received	Mar 21, 2025
Decision date	Dec 14, 2025
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cadwell Industries, Inc.
Location	Kennewick, WA, US
Contact	James Blevins
510(k) history	12 submissions · 12 cleared · 2014-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250851/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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