

K142774 Polysmith Sleep SystemFeb 18, 2015
145 days to decisionK142774 · Product code: **OLV** · Neurology
Source: <https://www.510kdatabase.net/k142774/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	Sep 26, 2014
Decision date	Feb 18, 2015
Days to decision	145 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Neurotronics, Inc.
Location	Gainesville, FL, US
Contact	David Pezet
510(k) history	9 submissions · 9 cleared · 1997-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k142774/> 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 30, 2026