

**K110967 ENTERPRISE ELECTROPHYSIOLOGY SYSTEM**Jun 30, 2011  
85 days to decisionK110967 · Product code: **OMC** · Neurology  
Source: <https://www.510kdatabase.net/k110967/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reduced- Montage Standard Electroencephalograph (OMC)
Date received	Apr 6, 2011
Decision date	Jun 30, 2011
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Neuralynx, Inc.</b>
Location	Bozeman, MT, US
Contact	MIKE JOHNSON
510(k) history	2 submissions · 2 cleared · 2011-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110967/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026