

**K033999 SEDLINE WITH FRONTAL PSI**Feb 6, 2004  
44 days to decisionK033999 · Product code: **OLW** · Neurology  
Source: <https://www.510kdatabase.net/k033999/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Index-generating Electroencephalograph Software (OLW)
Date received	Dec 24, 2003
Decision date	Feb 6, 2004
Days to decision	44 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Physiometrix, Inc.</b>
Location	Sunnyvale, CA, US
Contact	DAWN E FRAZER
510(k) history	22 submissions · 22 cleared · 1992-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033999/> 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 June 29, 2026