

**K042315 CEREBRAL STATE MONITOR - CSM**Jan 21, 2005  
148 days to decisionK042315 · Product code: **OLW** · Neurology  
Source: <https://www.510kdatabase.net/k042315/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Index-generating Electroencephalograph Software (OLW)
Date received	Aug 26, 2004
Decision date	Jan 21, 2005
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Danmeter A/S</b>
Location	Odense C, DK
Contact	HANNE NIELSEN
510(k) history	4 submissions · 4 cleared · 2003-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042315/> 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