

**K161027 Cadwell AmpliScan**Nov 8, 2016  
210 days to decisionK161027 · Product code: **OMA** · Neurology  
Source: <https://www.510kdatabase.net/k161027/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Amplitude-integrated Electroencephalograph (OMA)
Date received	Apr 12, 2016
Decision date	Nov 8, 2016
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cadwell Industries, Inc.</b>
Location	Kennewick, WA, US
Contact	John Cadwell
510(k) history	12 submissions · 12 cleared · 2014-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161027/> 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 24, 2026