

**K112052 CAREFUSION NICOLET EDX**Mar 15, 2012  
241 days to decisionK112052 · Product code: **GWF** · Neurology  
Source: <https://www.510kdatabase.net/k112052/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Evoked Response (GWF)
Date received	Jul 18, 2011
Decision date	Mar 15, 2012
Days to decision	241 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Carefusion 209, Inc.</b>
Location	Middleton, WI, US
Contact	ROBERT BURDGE
510(k) history	5 submissions · 5 cleared · 2011-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112052/> 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 14, 2026