

**K071969 SEN-4100 ELECTRIC STIMULATOR**Oct 6, 2008  
447 days to decisionK071969 · Product code: **GWF** · Neurology  
Source: <https://www.510kdatabase.net/k071969/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Evoked Response (GWF)
Date received	Jul 17, 2007
Decision date	Oct 6, 2008
Days to decision	447 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nihon Kohden America, Inc.</b>
Location	Foothill Ranch, CA, US
Contact	JACK COGGAN
510(k) history	166 submissions · 163 cleared · 1979-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k071969/> 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