

**K112485 H-WAVE**Dec 6, 2011  
99 days to decisionK112485 · Product code: **GZJ** · Neurology  
Source: <https://www.510kdatabase.net/k112485/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Aug 29, 2011
Decision date	Dec 6, 2011
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Electronic Waveform Lab, Inc.</b>
Location	Huntington Beach, CA, US
Contact	RYAN P HEANEY
510(k) history	1 submissions · 1 cleared · 2011-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112485/> 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 15, 2026