

**K991853 INTERACOUSTICS EP 15 ABR STAND ALONE UNIT**Oct 25, 1999  
146 days to decisionK991853 · Product code: **GWJ** · Neurology  
Source: <https://www.510kdatabase.net/k991853/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Jun 1, 1999
Decision date	Oct 25, 1999
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Idem (Int&amp;apos;L Dist. of Electronics For Medicine)</b>
Location	Benicia, CA, US
Contact	DONNA WARD
510(k) history	6 submissions · 6 cleared · 1998-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k991853/> 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 30, 2026