

**K925648 SMART-SCREENER (AUDITORY)**May 11, 1993  
183 days to decisionK925648 · Product code: **GWJ** · Neurology  
Source: <https://www.510kdatabase.net/k925648/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Nov 9, 1992
Decision date	May 11, 1993
Days to decision	183 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Intelligent Hearing Systems</b>
Location	North Miami, FL, US
Contact	EDWARD MISKIEL
510(k) history	13 submissions · 13 cleared · 1991-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k925648/> 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 31, 2026