

K090579 SMARTSCREENER-PLUS2Jul 7, 2009
126 days to decisionK090579 · Product code: **GWJ** · Neurology
Source: <https://www.510kdatabase.net/k090579/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Mar 3, 2009
Decision date	Jul 7, 2009
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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