

K122067 TYPE 1077 ACCUSCREENSep 27, 2012
73 days to decisionK122067 · Product code: **GWJ** · Neurology
Source: <https://www.510kdatabase.net/k122067/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Jul 16, 2012
Decision date	Sep 27, 2012
Days to decision	73 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Gn Otometrics
Location	Schaumburg, IL, US
Contact	TOM RINIKER
510(k) history	8 submissions · 8 cleared · 2008-2016

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