

K132957 MADSEN ACCUSCREEN TYPE 1077Feb 27, 2014
160 days to decisionK132957 · Product code: **GWJ** · Neurology
Source: <https://www.510kdatabase.net/k132957/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Sep 20, 2013
Decision date	Feb 27, 2014
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gn Otometrics
Location	Schaumburg, IL, US
Contact	DANIEL KAMM, P.E.
510(k) history	8 submissions · 8 cleared · 2008-2016

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