

K163326 SmartEPSep 29, 2017
305 days to decisionK163326 · Product code: **GWJ** · Neurology
Source: <https://www.510kdatabase.net/k163326/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Nov 28, 2016
Decision date	Sep 29, 2017
Days to decision	305 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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