

K070608 SMARTEP, MODEL M010000Jul 18, 2007
135 days to decisionK070608 · Product code: **GWJ** · Neurology
Source: <https://www.510kdatabase.net/k070608/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Mar 5, 2007
Decision date	Jul 18, 2007
Days to decision	135 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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