

K073384 SMART COUPLER, MODEL M015401Feb 28, 2008
87 days to decisionK073384 · Product code: **GWJ** · Neurology
Source: <https://www.510kdatabase.net/k073384/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Dec 3, 2007
Decision date	Feb 28, 2008
Days to decision	87 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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