

K043491 ENFANTTMMar 16, 2005
89 days to decisionK043491 · Product code: **GWE** · Neurology
Source: <https://www.510kdatabase.net/k043491/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Photic, Evoked Response (GWE)
Date received	Dec 17, 2004
Decision date	Mar 16, 2005
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diopsys, Inc.
Location	Pine Brook, NJ, US
Contact	JOSEPH FONTANETTA
510(k) history	2 submissions · 2 cleared · 2005-2011

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