

**K043367 GLAID OCULAR ELECTROPHYSIOLOGY DEVICE**Nov 17, 2005  
344 days to decisionK043367 · Product code: **GWE** · Neurology  
Source: <https://www.510kdatabase.net/k043367/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Photic, Evoked Response (GWE)
Date received	Dec 8, 2004
Decision date	Nov 17, 2005
Days to decision	344 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lace Electronica S.R.L.</b>
Location	Clearwater, FL, US
Contact	IAN P GORDON
510(k) history	1 submissions · 1 cleared · 2005-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043367/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 29, 2026