

**K052060 OPTI-AMP DC-POWERED**Aug 31, 2005  
33 days to decisionK052060 · Product code: **GWL** · Neurology  
Source: <https://www.510kdatabase.net/k052060/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Amplifier, Physiological Signal (GWL)
Date received	Jul 29, 2005
Decision date	Aug 31, 2005
Days to decision	33 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Intelligent Hearing Systems</b>
Location	North Miami, FL, US
Contact	EDWARD MISKIEL
510(k) history	13 submissions · 13 cleared · 1991-2017

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