

**K854535 INSERTION GAIN OPTIMIZER IGO-1000**Feb 20, 1986  
99 days to decisionK854535 · Product code: **ETW** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k854535/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Hearing Aid / Earphone And Analysis Systems (ETW)
Date received	Nov 13, 1985
Decision date	Feb 20, 1986
Days to decision	99 days
Third-party review	No

**APPLICANT**

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Company	<b>Madsen Electronics (Canada) , Ltd.</b>
Location	Oakville, Ontario, CA
Contact	GLEASON
510(k) history	17 submissions · 17 cleared · 1985-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k854535/>; 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 July 1, 2026