

**K081234 GN OTOMETRICS INSERT EARPHONES**Jul 14, 2008  
74 days to decisionK081234 · Product code: **EWO** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k081234/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	May 1, 2008
Decision date	Jul 14, 2008
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gn Otometrics</b>
Location	Schaumburg, IL, US
Contact	DANIEL SANSONETTI
510(k) history	8 submissions · 8 cleared · 2008-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081234/> 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 2, 2026