

**K061104 SPEECHLINK 100 TYPE 1053**May 3, 2006  
13 days to decisionK061104 · Product code: **ETW** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k061104/>**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	Apr 20, 2006
Decision date	May 3, 2006
Days to decision	13 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gn Otometrics A/S</b>
Location	Taastrup, DK
Contact	PER PAPE THOMSEN
510(k) history	6 submissions · 6 cleared · 2004-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061104/> 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 3, 2026