

**K110286 GN OTOMETRICS TYPE 1053 FREEFIT**Apr 28, 2011  
87 days to decisionK110286 · Product code: **ETW** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k110286/>**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	Jan 31, 2011
Decision date	Apr 28, 2011
Days to decision	87 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gn Otometrics A/S</b>
Location	Taastrup, DK
Contact	TOM RINIKER
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/k110286/> 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