

**K181586 Tinnitus Sound Generator Module**Jul 13, 2018  
28 days to decisionK181586 · Product code: **KLW** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k181586/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Masker, Tinnitus (KLW)
Date received	Jun 15, 2018
Decision date	Jul 13, 2018
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>GN Hearing A/S</b>
Location	Ballerup, DK
Contact	Lars Hagander
510(k) history	4 submissions · 4 cleared · 2018-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181586/> 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 May 27, 2026