

K180495 Tinnitus Sound Generator ModuleNov 30, 2018
277 days to decisionK180495 · Product code: **KLW** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k180495/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Masker, Tinnitus (KLW)
Date received	Feb 26, 2018
Decision date	Nov 30, 2018
Days to decision	277 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180495/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026