

K193303 Tinnitus Sound Generator ModuleFeb 20, 2020
83 days to decisionK193303 · Product code: **KLW** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k193303/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Masker, Tinnitus (KLW)
Date received	Nov 29, 2019
Decision date	Feb 20, 2020
Days to decision	83 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/k193303/> 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