

K260614 Tinnitus TherapyJun 10, 2026
105 days to decisionK260614 · Product code: **KLW** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k260614/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Masker, Tinnitus (KLW)
Date received	Feb 25, 2026
Decision date	Jun 10, 2026
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sivantos GmbH
Location	Erlangen, DE
Contact	Anja Ravn
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260614/> 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 July 11, 2026