

K161562 Sound Options Tinnitus TreatmentSep 28, 2016
114 days to decisionK161562 · Product code: **KLW** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k161562/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Masker, Tinnitus (KLW)
Date received	Jun 6, 2016
Decision date	Sep 28, 2016
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sound Options Tinnitus Treatments, Inc.
Location	Mississauga, CA
Contact	Michael Chrostowski
510(k) history	1 submissions · 1 cleared · 2016-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161562/> 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 June 2, 2026