

K221168 Tinnitogram Signal GeneratorFeb 1, 2023
285 days to decisionK221168 · Product code: **KLW** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k221168/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Masker, Tinnitus (KLW)
Date received	Apr 22, 2022
Decision date	Feb 1, 2023
Days to decision	285 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Goldeneer Company, Inc.
Location	Santa Clarita, CA, US
Contact	Daehee Lee
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221168/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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