

K233435 Peace N Quiet (0.7.0)Feb 27, 2024
137 days to decisionK233435 · Product code: **KLW** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k233435/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Masker, Tinnitus (KLW)
Date received	Oct 13, 2023
Decision date	Feb 27, 2024
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pnq Health
Location	Minnetonka, MN, US
Contact	Kurtis Goos
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	RQM+
Contact	Alexia Haralambous

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233435/> 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 14, 2026