

K242214 SonuApr 24, 2025
269 days to decisionK242214 · Product code: **QZC** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k242214/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	External Mechanical Stimulator For The Relief Of Congestion (QZC)
Date received	Jul 29, 2024
Decision date	Apr 24, 2025
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sound Health Systems, Inc.
Location	Los Altos, CA, US
Contact	Parameswaran Gopi
510(k) history	2 submissions · 1 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	RQM+
Contact	Pierre Bounaud

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242214/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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