

K223848 Intrisound™ Tuned Lumen® 155 Hearing AidsSep 8, 2023
260 days to decisionK223848 · Product code: **QUH** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k223848/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Self-fitting Air-conduction Hearing Aid, Over The Counter (QUH)
Date received	Dec 22, 2022
Decision date	Sep 8, 2023
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tuned , Ltd.
Location	Gan Yoshiya, IL
Contact	Orit Ianco
510(k) history	2 submissions · 2 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	ProMedoss, Inc.
Contact	Shoshana (Shosh) Friedman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**CLINICAL EVIDENCE - NCT05869266****Tuned App Self-Fitting vs. Professional Fitting**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	56 patients (actual)
Study sites	1 site
Condition studied	Hearing Loss
Primary purpose	Other
Study type	Interventional
Study design	Crossover
Masking	Open label
Completion date	Jul 15, 2023
Sponsor	Tuned Ltd. (Industry)

Primary outcome

Comparison of self fitting and professional fitting by COSI scores

Secondary outcome

Comparison of self fitting and professional fitting by IOI-HA scores

Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05869266