

**K251208 Tuned Self-Fitting Mobile App**Sep 26, 2025  
161 days to decisionK251208 · Product code: **SCR** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k251208/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Air-conduction Hearing Aid Software (SCR)
Date received	Apr 18, 2025
Decision date	Sep 26, 2025
Days to decision	161 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tuned , Ltd.</b>
Location	Gan Yoshiya, IL
Contact	Omri Gavish
510(k) history	2 submissions · 2 cleared · 2023-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>ProMedoss, Inc.</b>
Contact	Shoshana Friedman

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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251208/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026