

K254044 Hearing assist

Jul 13, 2026
208 days to decision

K254044 · Product code: **SCR** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k254044/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Air-conduction Hearing Aid Software (SCR)
Date received	Dec 17, 2025
Decision date	Jul 13, 2026
Days to decision	208 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Meta Platform Technologies, LLC
Location	Burlingame, CA, US
Contact	Lucas Fernandez
510(k) history	1 submissions · 1 cleared · 2026-2026