

K243150 Nuance Audio Hearing Aid SoftwareJan 31, 2025
123 days to decisionK243150 · Product code: **SCR** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k243150/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Air-conduction Hearing Aid Software (SCR)
Date received	Sep 30, 2024
Decision date	Jan 31, 2025
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Luxottica Group S.P.A.
Location	Milan, IT
Contact	Giulia Cuccato
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243150/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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