

K231545 hearOAEOct 27, 2023
150 days to decisionK231545 · Product code: **EWO** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k231545/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	May 30, 2023
Decision date	Oct 27, 2023
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hearx SA (Pty) , Ltd.
Location	Pretoria, ZA
Contact	Seline Van Der Wat
510(k) history	2 submissions · 2 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231545/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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