

# K223137 Lexie Lumen Self-Fitting OTC Hearing Aids with Lexie Application

Mar 14, 2023  
161 days to decisionK223137 · Product code: **QUH** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k223137/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Self-fitting Air-conduction Hearing Aid, Over The Counter (QUH)
Date received	Oct 4, 2022
Decision date	Mar 14, 2023
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>Hearx SA (Pty) , Ltd.</b>
Location	Pretoria, ZA
Contact	Seline Van Der Wat
510(k) history	2 submissions · 2 cleared · 2023-2023

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