

K191372 LyraJul 15, 2019
54 days to decisionK191372 · Product code: **EWO** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k191372/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	May 22, 2019
Decision date	Jul 15, 2019
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Interacoustics A/S
Location	Minnesota, MN, US
Contact	Erik Nielsen
510(k) history	17 submissions · 17 cleared · 2006-2020

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