

K192652 TRVMay 27, 2020
246 days to decisionK192652 · Product code: **LXV** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k192652/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Vestibular Analysis (LXV)
Date received	Sep 24, 2019
Decision date	May 27, 2020
Days to decision	246 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192652/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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