

**K200529 Orion**Aug 12, 2020  
163 days to decisionK200529 · Product code: **LXV** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k200529/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Vestibular Analysis (LXV)
Date received	Mar 2, 2020
Decision date	Aug 12, 2020
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Interacoustics A/S</b>
Contact	Erik Nielsen

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200529/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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