

**K234095 OtoNova/OtoNova Pro**Jun 21, 2024  
178 days to decisionK234095 · Product code: **EWO** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k234095/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	Dec 26, 2023
Decision date	Jun 21, 2024
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Otodynamics</b>
Location	Hatfield, Hertfordshire, GB
Contact	Daniel Budd
510(k) history	1 submissions · 1 cleared · 2024-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Rook Quality Systems</b>
Contact	Chandler Thames

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

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