FDA 510(k) Premarket Notification

K234095 OtoNova/OtoNova Pro

CLEARED

Jun 21, 2024
178 days to decision

K234095 · Product code: **EWO** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k234095/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Rook Quality Systems**
Contact	Chandler Thames

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