

K173567 SeraFeb 14, 2018
86 days to decisionK173567 · Product code: **EWO** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k173567/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	Nov 20, 2017
Decision date	Feb 14, 2018
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173567/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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