

K151025 iHearTestDec 29, 2015
257 days to decisionK151025 · Product code: **EWO** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k151025/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	Apr 16, 2015
Decision date	Dec 29, 2015
Days to decision	257 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ihear Medical, Inc.
Location	San Leandro, CA, US
Contact	ANGELA LEE FOREMAN
510(k) history	1 submissions · 1 cleared · 2015-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151025/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 3, 2026