

**K935348 ODYSSEY CLINICAL AUDIOMETER**Feb 9, 1994  
96 days to decisionK935348 · Product code: **EWO** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k935348/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	Nov 5, 1993
Decision date	Feb 9, 1994
Days to decision	96 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Qualitone</b>
Location	Mchenry, IL, US
Contact	BRUCE BROWN
510(k) history	39 submissions · 39 cleared · 1976-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k935348/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 4, 2026