

**K092089 CLARUJUST**Mar 10, 2010  
244 days to decisionK092089 · Product code: **EWO** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k092089/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	Jul 9, 2009
Decision date	Mar 10, 2010
Days to decision	244 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Audigence, Inc.</b>
Location	Melbourne, FL, US
Contact	CRAIG PAGAN
510(k) history	1 submissions · 1 cleared · 2010-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k092089/> 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 June 21, 2026