

**K130514 AUDIFON ARRIVA CIC, IS, IS+, M, S, S+, X TRT,  
AUDIFON VICO, AUDIFON PRADO, AUDIFON ELIA, CIC, IS, IS+,  
M, S TRT**Nov 21, 2013  
267 days to decisionK130514 · Product code: **KLW** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k130514/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Masker, Tinnitus (KLW)
Date received	Feb 27, 2013
Decision date	Nov 21, 2013
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Audifon-USA, Inc.</b>
Location	Debary, FL, US
Contact	JANE E PERRONE
510(k) history	4 submissions · 4 cleared · 2009-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130514/>; 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 8, 2026