

**K252751 Earflo (EF001)**Feb 10, 2026  
165 days to decisionK252751 · Product code: **MJV** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k252751/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Inflation, Middle Ear (MJV)
Date received	Aug 29, 2025
Decision date	Feb 10, 2026
Days to decision	165 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Earflo, Inc.</b>
Location	San Carlos, CA, US
Contact	Intan Oldakowska
510(k) history	1 submissions · 1 cleared · 2026-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252751/> 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 May 13, 2026