

**K974235 AMPLAID AM50**Feb 10, 1998  
90 days to decisionK974235 · Product code: **ETY** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k974235/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tester, Auditory Impedance (ETY)
Date received	Nov 12, 1997
Decision date	Feb 10, 1998
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Amplifon S.P.A.</b>
Location	Deer Field, IL, US
Contact	DANIEL KAMM
510(k) history	8 submissions · 8 cleared · 1997-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k974235/> 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 30, 2026