

**K965088 M11 SERIES: M11, M11M**Jan 24, 1997  
36 days to decisionK965088 · Product code: **ESD** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k965088/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Dec 19, 1996
Decision date	Jan 24, 1997
Days to decision	36 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Philips Hearing Instruments Co.</b>
Location	Mahwah, NJ, US
Contact	ROBERT MARTIN
510(k) history	20 submissions · 20 cleared · 1991-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k965088/> 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 5, 2026