

**K954794 OTICON**Nov 13, 1995  
26 days to decisionK954794 · Product code: **ESD** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k954794/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Oct 18, 1995
Decision date	Nov 13, 1995
Days to decision	26 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Oticon, Inc.</b>
Location	Somerset, NJ, US
Contact	PREBEN BRUNVED
510(k) history	9 submissions · 9 cleared · 1993-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k954794/> 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