

**K862621 I22 INITIALES**Aug 1, 1986  
22 days to decisionK862621 · Product code: **ERA** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k862621/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Otoscope (ERA)
Date received	Jul 10, 1986
Decision date	Aug 1, 1986
Days to decision	22 days
Third-party review	No

**APPLICANT**

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Company	<b>Oticon Corp.</b>
Location	Mchenry, IL, US
Contact	HENNING V FALSTER
510(k) history	57 submissions · 57 cleared · 1978-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k862621/>, 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