

**K941635 INTRA S, INTRA SH**May 4, 1994  
30 days to decisionK941635 · Product code: **ESD** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k941635/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Apr 4, 1994
Decision date	May 4, 1994
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Starkey Laboratories, Inc.</b>
Location	Mchenry, IL, US
Contact	RICK STROMBERG
510(k) history	60 submissions · 60 cleared · 1977-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k941635/> 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 15, 2026