

**K971845 HEARTLAND TECHNOLOGIES, ITE, ITC, CIC**Aug 15, 1997  
88 days to decisionK971845 · Product code: **ESD** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k971845/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	May 19, 1997
Decision date	Aug 15, 1997
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sound Hearing Instruments, Inc.</b>
Location	Minneapolis, MN, US
Contact	DALE WOODARD
510(k) history	1 submissions · 1 cleared · 1997-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971845/> 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