

**K920657 DI CUSTOM IN THE EAR AND IN THE CANAL**Mar 31, 1992  
48 days to decisionK920657 · Product code: **ESD** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k920657/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Feb 12, 1992
Decision date	Mar 31, 1992
Days to decision	48 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Dakota Laboratories, Inc.</b>
Location	Lake Andes, SD, US
Contact	DON TRUMMER
510(k) history	1 submissions · 1 cleared · 1992-1992

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k920657/> 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 6, 2026