

**K971158 DUALINE 400 CIC**Jun 13, 1997  
77 days to decisionK971158 · Product code: **ESD** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k971158/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Mar 28, 1997
Decision date	Jun 13, 1997
Days to decision	77 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Bernafon-Maico, Inc.</b>
Location	Eden Prairie, MN, US
Contact	RAY ENROTH
510(k) history	9 submissions · 9 cleared · 1996-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971158/> 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