

**K935400 FONIX 3500 HEARING AID ANALYZER**Jan 14, 1994  
66 days to decisionK935400 · Product code: **ETW** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k935400/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Hearing Aid / Earphone And Analysis Systems (ETW)
Date received	Nov 9, 1993
Decision date	Jan 14, 1994
Days to decision	66 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Frye Electronics, Inc.</b>
Location	Mchenry, IL, US
Contact	GEORGE J FRYE
510(k) history	13 submissions · 13 cleared · 1980-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k935400/> 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 9, 2026