

**K914816 AMERICAN ARTIFICIAL LARYNX**Feb 12, 1993  
476 days to decisionK914816 · Product code: **ESE** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k914816/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Larynx, Artificial (battery-powered) (ESE)
Date received	Oct 25, 1991
Decision date	Feb 12, 1993
Days to decision	476 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ultravoice, Ltd.</b>
Location	Paoli, PA, US
Contact	DAVID R BARAFF
510(k) history	1 submissions · 1 cleared · 1993-1993

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k914816/> 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