

**K854158 RESNICK EMITTER, ARTIFICIAL LARYNX**Dec 13, 1985  
63 days to decisionK854158 · Product code: **ESE** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k854158/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Larynx, Artificial (battery-powered) (ESE)
Date received	Oct 11, 1985
Decision date	Dec 13, 1985
Days to decision	63 days
Third-party review	No

**APPLICANT**

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Company	<b>Dynamed Audio, Inc.</b>
Location	Natrona Heights, PA, US
Contact	JOSEPH A RESNICK
510(k) history	1 submissions · 1 cleared · 1985-1985

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k854158/>; 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