

**K823749 LOW PRESSURE BLOM-SINGER VOICE PROSTHES**Jan 7, 1983  
25 days to decisionK823749 · Product code: **EWL** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k823749/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	Dec 13, 1982
Decision date	Jan 7, 1983
Days to decision	25 days
Third-party review	No

**APPLICANT**

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Company	<b>Bivona Medical Technologies</b>
Location	Mchenry, IL, US
510(k) history	50 submissions · 50 cleared · 1978-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k823749/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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