

**K800563 BLOM-SINGER DUCKBILL VOICE PROSTHESIS**Mar 25, 1980  
12 days to decisionK800563 · Product code: **EWL** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k800563/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	Mar 13, 1980
Decision date	Mar 25, 1980
Days to decision	12 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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