

K812982 BLOM-SINGER VOICE PROSTHESISNov 24, 1981
32 days to decisionK812982 · Product code: **EWL** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k812982/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	Oct 23, 1981
Decision date	Nov 24, 1981
Days to decision	32 days
Third-party review	No

APPLICANT

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

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