

K881011 BIVONA ULTRA LOW RESISTANCE VOICE PROSTHESISMay 13, 1988
64 days to decisionK881011 · Product code: **EWL** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k881011/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	Mar 10, 1988
Decision date	May 13, 1988
Days to decision	64 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k881011/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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