

K915761 BIVONA-COLORADO VOICE PROSTHESISJun 29, 1992
188 days to decisionK915761 · Product code: **EWL** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k915761/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	Dec 24, 1991
Decision date	Jun 29, 1992
Days to decision	188 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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