

K861088 BIVONA ECONOMY DUCKBILL VOICE PROSTHESISApr 2, 1986
12 days to decisionK861088 · Product code: **EWL** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k861088/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Laryngeal (taub) (EWL) |
| Date received | Mar 21, 1986 |
| Decision date | Apr 2, 1986 |
| Days to decision | 12 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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