

K820737 PERISCOPE VOICE PROSTHESISApr 9, 1982
22 days to decisionK820737 · Product code: **EWL** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k820737/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	Mar 18, 1982
Decision date	Apr 9, 1982
Days to decision	22 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k820737/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026