

K810020 PANJE VOICE PROSTHESISFeb 5, 1981
31 days to decisionK810020 · Product code: **EWL** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k810020/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	Jan 5, 1981
Decision date	Feb 5, 1981
Days to decision	31 days
Third-party review	No

APPLICANT

Company	Xomed, Inc.
Location	Arnold, MO, US
510(k) history	82 submissions · 81 cleared · 1976-2000

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Device record: <https://www.510kdatabase.net/k810020/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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