

K812864 SILASTIC VOICE PROSTHESISNov 24, 1981
42 days to decisionK812864 · Product code: **EWL** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k812864/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Laryngeal (taub) (EWL)
Date received	Oct 13, 1981
Decision date	Nov 24, 1981
Days to decision	42 days
Third-party review	No

APPLICANT

Company	Dow Corning Corp. Healthcare Industries Materials
Location	Mchenry, IL, US
510(k) history	31 submissions · 31 cleared · 1976-1985

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Device record: <https://www.510kdatabase.net/k812864/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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