

K823118 SAYJan 7, 1983
78 days to decisionK823118 · Product code: **ESE** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k823118/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Larynx, Artificial (battery-powered) (ESE)
Date received	Oct 21, 1982
Decision date	Jan 7, 1983
Days to decision	78 days
Third-party review	No

APPLICANT

Company	Kells Medical, Inc.
Location	Mchenry, IL, US
510(k) history	12 submissions · 11 cleared · 1982-1993

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Device record: <https://www.510kdatabase.net/k823118/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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