FDA 510(k) Premarket Notification

K823118 SAY

CLEARED

Jan 7, 1983
78 days to decision

K823118 · 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