FDA 510(k) Premarket Notification

K914816 AMERICAN ARTIFICIAL LARYNX

CLEARED

Feb 12, 1993
476 days to decision

K914816 · Product code: **ESE** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k914816/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Larynx, Artificial (battery-powered) (ESE)
Date received	Oct 25, 1991
Decision date	Feb 12, 1993
Days to decision	476 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Ultravoice, Ltd.**
Location	Paoli, PA, US
Contact	DAVID R BARAFF
510(k) history	1 submissions · 1 cleared · 1993-1993