FDA 510(k) Premarket Notification

K862621 I22 INITIALES

CLEARED

Aug 1, 1986
22 days to decision

K862621 · Product code: **ERA** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k862621/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Otoscope (ERA)
Date received	Jul 10, 1986
Decision date	Aug 1, 1986
Days to decision	22 days
Third-party review	No

APPLICANT

Company	**Oticon Corp.**
Location	Mchenry, IL, US
Contact	HENNING V FALSTER
510(k) history	57 submissions · 57 cleared · 1978-1996