FDA 510(k) Premarket Notification

K790228 EARETTE HEARING AID

CLEARED

Feb 12, 1979
10 days to decision

K790228 · Product code: **ESD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k790228/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Feb 2, 1979
Decision date	Feb 12, 1979
Days to decision	10 days
Third-party review	No

APPLICANT

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