FDA 510(k) Premarket Notification

CLEARED

K801002 OTICON EARETTE HEARING AID #E17 HC

May 28, 1980
30 days to decision

K801002 · Product code: **ESD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k801002/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Apr 28, 1980
Decision date	May 28, 1980
Days to decision	30 days
Third-party review	No

APPLICANT

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