FDA 510(k) Premarket Notification

K960284 OTICON /PRIMOFOCUS (PF)

CLEARED

Mar 7, 1996
48 days to decision

K960284 · Product code: **ESD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k960284/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Jan 19, 1996
Decision date	Mar 7, 1996
Days to decision	48 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Oticon, Inc.**
Location	Somerset, NJ, US
Contact	PREBEN BRUNVED
510(k) history	9 submissions · 9 cleared · 1993-1997