FDA 510(k) Premarket Notification

K913390 M32 IN-THE-EAR HEARING AID

CLEARED

Aug 26, 1991
28 days to decision

K913390 · Product code: **ESD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k913390/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Jul 29, 1991
Decision date	Aug 26, 1991
Days to decision	28 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Philips Hearing Instruments Co.**
Location	Mahwah, NJ, US
Contact	ROBERT MARTIN
510(k) history	20 submissions · 20 cleared · 1991-1997