FDA 510(k) Premarket Notification

K965088 M11 SERIES: M11, M11M

CLEARED

Jan 24, 1997
36 days to decision

K965088 · Product code: **ESD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k965088/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Dec 19, 1996
Decision date	Jan 24, 1997
Days to decision	36 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