FDA 510(k) Premarket Notification

K950691 MIRACLE-EAR MODEL PBM PROGRAMMABLE HEARING AID

CLEARED

Mar 31, 1995
45 days to decision

K950691 · Product code: **ESD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k950691/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Feb 14, 1995
Decision date	Mar 31, 1995
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Miracle-Ear, Inc.**
Location	Golden Valley, MN, US
Contact	MELANIE RASKA
510(k) history	65 submissions · 65 cleared · 1990-1997