FDA 510(k) Premarket Notification

K901388 SEARS MODEL LM9091 IN-THE-EAR HEARING INSTRUMENT

CLEARED

Apr 16, 1990
21 days to decision

K901388 · Product code: **ESD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k901388/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Mar 26, 1990
Decision date	Apr 16, 1990
Days to decision	21 days
Third-party review	No

APPLICANT

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