FDA 510(k) Premarket Notification

K915711 IN THE EAR HEARING AID

CLEARED

Jun 10, 1992
188 days to decision

K915711 · Product code: **ESD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k915711/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Dec 5, 1991
Decision date	Jun 10, 1992
Days to decision	188 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Zenith-Omni H.C., Inc.**
Location	New Haven, CT, US
Contact	RICHARD E MCMAHON
510(k) history	1 submissions · 1 cleared · 1992-1992