FDA 510(k) Premarket Notification

K915450 IN THE EAR HEARING AID

CLEARED

Feb 27, 1992
84 days to decision

K915450 · Product code: **ESD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k915450/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Dec 5, 1991
Decision date	Feb 27, 1992
Days to decision	84 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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