FDA 510(k) Premarket Notification

K823588 PERSONAL ROMEAR

CLEARED

Apr 27, 1983
142 days to decision

K823588 · Product code: **ESD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k823588/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Dec 6, 1982
Decision date	Apr 27, 1983
Days to decision	142 days
Third-party review	No

APPLICANT

Company	**Romear Mfg., Inc.**
Location	Walker, MI, US
510(k) history	1 submissions · 1 cleared · 1983-1983