

K823588 PERSONAL ROMEARApr 27, 1983
142 days to decisionK823588 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k823588/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 6, 2026