FDA 510(k) Premarket Notification

K811522 RE-HP SERIES HEARING AIDS

CLEARED

Jun 26, 1981
28 days to decision

K811522 · Product code: **ESD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k811522/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	May 29, 1981
Decision date	Jun 26, 1981
Days to decision	28 days
Third-party review	No

APPLICANT

Company	**Radioear Corp.**
Location	Mchenry, IL, US
510(k) history	14 submissions · 14 cleared · 1976-1984