FDA 510(k) Premarket Notification

K830790 PERSONAL AMPLIFIER MODULE

CLEARED

Jul 12, 1983
120 days to decision

K830790 · Product code: **ESD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k830790/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Mar 14, 1983
Decision date	Jul 12, 1983
Days to decision	120 days
Third-party review	No

APPLICANT

Company	**Electone, Inc.**
Location	Mchenry, IL, US
510(k) history	73 submissions · 73 cleared · 1981-1997