FDA 510(k) Premarket Notification

K953052 AM 260 K-AMP

CLEARED

Aug 15, 1995
46 days to decision

K953052 · Product code: **ESD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k953052/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Jun 30, 1995
Decision date	Aug 15, 1995
Days to decision	46 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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