FDA 510(k) Premarket Notification

K823788 MECON I

CLEARED

Mar 29, 1983
103 days to decision

K823788 · Product code: **ESD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k823788/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Dec 16, 1982
Decision date	Mar 29, 1983
Days to decision	103 days
Third-party review	No

APPLICANT

Company	**Mecon Labs**
Location	Mchenry, IL, US
510(k) history	2 submissions · 2 cleared · 1983-1985