FDA 510(k) Premarket Notification

K002232 AEDEFIBRILLATOR

CLEARED

Dec 6, 2000
135 days to decision

K002232 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k002232/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Jul 24, 2000
Decision date	Dec 6, 2000
Days to decision	135 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Medical Research Laboratories, Inc.**
Location	Mchenry, IL, US
Contact	JOEL ORLINSKY
510(k) history	19 submissions · 15 cleared · 1981-2002