FDA 510(k) Premarket Notification

K010207 PORTABLE INSTENSIVE CARE UNIT

CLEARED

Jun 14, 2001
142 days to decision

K010207 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k010207/

SUBMISSION DETAILS

Decision	Substantially Equivalent - ST
Submission type	Special
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Jan 23, 2001
Decision date	Jun 14, 2001
Days to decision	142 days
Third-party review	No

APPLICANT

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