FDA 510(k) Premarket Notification

K993533 POWERHEART AECD

CLEARED

Jan 24, 2000
97 days to decision

K993533 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k993533/

SUBMISSION DETAILS

Decision	Substantially Equivalent - ST
Submission type	Special
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Oct 19, 1999
Decision date	Jan 24, 2000
Days to decision	97 days
Third-party review	No

APPLICANT

Company	**Cardiac Science, Inc.**
Location	Minnetonka, MN, US
Contact	STAN E TILLMAN
510(k) history	10 submissions · 8 cleared · 1997-2006