FDA 510(k) Premarket Notification

K012197 POWERHEART CARDIAC RHYTHM MODULE

CLEARED

Nov 16, 2001
126 days to decision

K012197 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k012197/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Jul 13, 2001
Decision date	Nov 16, 2001
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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