K052161 POWERHEART AED G3 (MODEL 9390E), POWERHEART AED G3 AUTOMATIC (MODEL 9390A)

CLEARED

Oct 21, 2005
73 days to decision

K052161 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k052161/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Aug 9, 2005
Decision date	Oct 21, 2005
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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