FDA 510(k) Premarket Notification

K103651 CARDIOMED

CLEARED

Oct 4, 2011
294 days to decision

K103651 · Product code: **LDD** · Cardiovascular
Source: https://www.510kdatabase.net/k103651/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dc-defibrillator, Low-energy, (including Paddles) (LDD)
Date received	Dec 14, 2010
Decision date	Oct 4, 2011
Days to decision	294 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cardio Medical Products, Inc.**
Location	Rockaway, NJ, US
Contact	NICK MENDISE
510(k) history	3 submissions · 3 cleared · 2011-2011