FDA 510(k) Premarket Notification

K022107 CARDIASSIST COUNTERPULSATION SYSTEM, MODEL MARK 3000

CLEARED

Aug 8, 2002
41 days to decision

K022107 · Product code: **DRN** · Cardiovascular
Source: https://www.510kdatabase.net/k022107/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Counter-pulsating, External (DRN)
Date received	Jun 28, 2002
Decision date	Aug 8, 2002
Days to decision	41 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cardiomedics, Inc.**
Location	Torrance, CA, US
Contact	GARY CLARK
510(k) history	5 submissions · 5 cleared · 1987-2005