FDA 510(k) Premarket Notification

K062970 I-PAD

CLEARED

Jan 22, 2008
480 days to decision

K062970 · Product code: **MKJ** · Cardiovascular
Source: https://www.510kdatabase.net/k062970/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated External Defibrillators (non-wearable) (MKJ)
Date received	Sep 29, 2006
Decision date	Jan 22, 2008
Days to decision	480 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cu Medical Systems, Inc.**
Location	Stillwater, MN, US
Contact	ELAINE DUNCAN
510(k) history	1 submissions · 1 cleared · 2008-2008