

K062970 I-PADJan 22, 2008
480 days to decisionK062970 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k062970/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 25, 2026