

**K053247 VALIDATE CARDIAC MARKER (CM1) CALIBRATION
VERIFICATION TEST SET**

Jan 13, 2006
53 days to decision

K053247 · Product code: JJY · Chemistry
Source: <https://www.510kdatabase.net/k053247/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Nov 21, 2005
Decision date	Jan 13, 2006
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Maine Standards Co.
Location	Windham, ME, US
Contact	CHRISTINE BEACH
510(k) history	23 submissions · 23 cleared · 2001-2013

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k053247/>; 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 8, 2026