

**K012120 VALIDATE CHEM 4 CALIBRATION VERIFICATION
TEST SET, MODEL 10004**Aug 20, 2001
45 days to decisionK012120 · Product code: JJY · Chemistry
Source: <https://www.510kdatabase.net/k012120/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Jul 6, 2001
Decision date	Aug 20, 2001
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012120/> 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