

**K012117 VALIDATE CHEM 1 CALIBRATION VERIFICATION  
TEST SET, MODEL 10001**Aug 20, 2001  
45 days to decisionK012117 · Product code: JJY · Chemistry  
Source: <https://www.510kdatabase.net/k012117/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012117/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 9, 2026