

**K142964 VALIDATE Anemia Calibration Verification/ Linearity  
Test Kit**Apr 30, 2015  
198 days to decisionK142964 · Product code: **JJY** · Chemistry  
Source: <https://www.510kdatabase.net/k142964/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Oct 14, 2014
Decision date	Apr 30, 2015
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Maine Standards Company, LLC</b>
Location	Windham, ME, US
Contact	James Champlin
510(k) history	7 submissions · 7 cleared · 2011-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k142964/>; 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 1, 2026