

**K133550 VALIDATE FERRITIN CALIBRATION VERIFICATION/  
LINEARITY TEST KIT**

Feb 5, 2014  
78 days to decision

K133550 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k133550/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Nov 19, 2013
Decision date	Feb 5, 2014
Days to decision	78 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 W 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/k133550/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).  
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