

**K123127 VALIDATE PSA CALIBRATION VERIFICATION/
LINEARITY TEST KIT MODEL 406**Jun 14, 2013
253 days to decisionK123127 · Product code: **JJX** · Immunology
Source: <https://www.510kdatabase.net/k123127/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Oct 4, 2012
Decision date	Jun 14, 2013
Days to decision	253 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123127/>. 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