

**K122534 IMMULITE 1000 THIRD GENERATION PSA
CALIBRATION VERIFICATION MATERIAL**Mar 14, 2013
206 days to decisionK122534 · Product code: **JJX** · Immunology
Source: <https://www.510kdatabase.net/k122534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Aug 20, 2012
Decision date	Mar 14, 2013
Days to decision	206 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics, Inc.
Location	New York, NY, US
Contact	Garo Mimaryan
Website	https://www.siemens-healthineers.com
510(k) history	152 submissions · 151 cleared · 2008-2026

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