

K131536 IMMULITE 2000 PSA CALIBRATION VERIFICATION MATERIALAug 12, 2013
75 days to decisionK131536 · Product code: **JJX** · Immunology
Source: <https://www.510kdatabase.net/k131536/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	May 29, 2013
Decision date	Aug 12, 2013
Days to decision	75 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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