

**K132391 IMMULITE 2000 ANTI-TG AB CALIBRATION
 VERIFICATION MATERIAL, IMMULITE 2000 ANTI-TPO AB
 CALIBRATION VERIFICATIN MATERIAL**

Sep 20, 2013
 50 days to decision

K132391 · Product code: **JJX** · Immunology
 Source: <https://www.510kdatabase.net/k132391/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Aug 1, 2013
Decision date	Sep 20, 2013
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Helathcare Diagnostics, Inc.
Location	West Sacramento, CA, US
Contact	Garo Mimaryan
510(k) history	2 submissions · 2 cleared · 2013-2013

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k132391/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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