

K141444 IMMULITE 2000Jul 9, 2014
37 days to decisionK141444 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k141444/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Jun 2, 2014
Decision date	Jul 9, 2014
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary
Other names	CORTISOL CALIBRATION VERIFICATION MATERIAL, FOLIC ACID CALIBRATION VERIFICATION MATERIAL, VITAMIN B12 CAL

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k141444/> 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 May 14, 2026