

**K140541 IMMULITE 2000: C-PEPTIDE CALIBRATION  
VERIFICATION MATERIAL, SHBG CALIBRATION  
VERIFICATION MATERIAL, TOTAL TESTOSTERONE C**Apr 1, 2014  
28 days to decisionK140541 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k140541/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Mar 4, 2014
Decision date	Apr 1, 2014
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140541/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 28, 2026