

**K140818 IMMULITE: 2000 FREE T4 CALIBRATION  
 VERIFICATION MATERIAL, 2000 IGF-I CALIBRATION  
 VERIFICATION MATERIAL, 2000 PROLACTIN C**

May 1, 2014  
 30 days to decision

K140818 · Product code: **JJX** · Chemistry  
 Source: <https://www.510kdatabase.net/k140818/>

**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	Apr 1, 2014
Decision date	May 1, 2014
Days to decision	30 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	Ernest Joseph
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/k140818/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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