

**K133124 IMMULITE 2000**Oct 25, 2013  
25 days to decisionK133124 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k133124/>**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	Sep 30, 2013
Decision date	Oct 25, 2013
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary
Other names	TOTAL T3 CALIBRATION VERIFICATION MATERIAL, TOTAL T4 CALIBRATION VERIFICATION MATERIAL, TOTAL TBG CALIBRA

**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/k133124/> 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 14, 2026