

**K112523 IMMULITE 2000 3GALLERGY SPECIFIC IGE ASSAY  
KIT**Jan 6, 2012  
128 days to decisionK112523 · Product code: **DHB** · Immunology  
Source: <https://www.510kdatabase.net/k112523/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Aug 31, 2011
Decision date	Jan 6, 2012
Days to decision	128 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/k112523/> 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