

**K083314 IMMULITE 2000 3GALLERGY SPECIFIC IGE ASSAY
KIT**

Mar 11, 2009
121 days to decision

K083314 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k083314/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Nov 10, 2008
Decision date	Mar 11, 2009
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics
Location	Newark, DE, US
Contact	CLARE SANTULLI
510(k) history	92 submissions · 92 cleared · 2008-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k083314/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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