

**K091289 IMMULITE 2000 3GALLERGY SPECIFIC IGE ASSAY
KIT**

Aug 6, 2009
97 days to decision

K091289 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k091289/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	May 1, 2009
Decision date	Aug 6, 2009
Days to decision	97 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/k091289/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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