

K132801 IMMULITE 2000 SYSTEMS 3GALLERGY SPECIFIC IGE ASSAY

May 28, 2014
257 days to decision

K132801 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k132801/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Sep 13, 2013
Decision date	May 28, 2014
Days to decision	257 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics, Inc.
Location	New York, NY, US
Contact	Ernest Joseph
Website	https://www.siemens-healthineers.com
510(k) history	152 submissions · 151 cleared · 2008-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k132801/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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