

K133122 IMMULITE 2000Oct 30, 2013
30 days to decisionK133122 · Product code: **JJX** · Immunology
Source: <https://www.510kdatabase.net/k133122/>**SUBMISSION DETAILS**

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 30, 2013
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary
Other names	3GALLERGY SPECIFIC IGE CONTROL VERIFICATION MATERIAL (CVM), TOTAL IGE CONTROL VERIFICATION MATERIAL (CVM)

APPLICANT

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

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