

K090594 DIMENSION VISTA IMMUNOGLOBULIN A FLEX REAGENT CARTRIDGE (IGA), AND DIMENSION VISTA IMMUNOGLOBULIN M FLEX REAGENT CARTRID

Apr 29, 2009
55 days to decision

K090594 · Product code: **CFN** · Immunology
Source: <https://www.510kdatabase.net/k090594/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Mar 5, 2009
Decision date	Apr 29, 2009
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics
Location	Newark, DE, US
Contact	KATHLEEN A DRAY-LYONS
510(k) history	92 submissions · 92 cleared · 2008-2025

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Device record: <https://www.510kdatabase.net/k090594/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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