

**K092283 DIMENSION VISTA IMMUNOGLOBULIN IGG
SUBCLASSSS 1FLEX REAGENT CARTRIDGE, DIMENSION VISTA
IMMUNOGLOBULIN IGG**

Oct 21, 2009
84 days to decision

K092283 · Product code: **DFZ** · Immunology
Source: <https://www.510kdatabase.net/k092283/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Igg (gamma Chain Specific), Antigen, Antiserum, Control (DFZ)
Date received	Jul 29, 2009
Decision date	Oct 21, 2009
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k092283/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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