

**K061338 DIMENSION VISTA IGA FLEX REAGENT CARTRIDGE
ASSAY**Jul 6, 2006
52 days to decisionK061338 · Product code: **CFN** · Immunology
Source: <https://www.510kdatabase.net/k061338/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	May 15, 2006
Decision date	Jul 6, 2006
Days to decision	52 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	KATHLEEN DRAY-LYONS
510(k) history	343 submissions · 343 cleared · 1978-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061338/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 19, 2026