

**K061845 DIMENSION VISTA IGM FLEX REAGENT CARTRIDGE  
AND PROTEIN 1 CALIBRATOR AND CONTROL L, M AND H**Aug 24, 2006  
56 days to decisionK061845 · Product code: **CFN** · Immunology  
Source: <https://www.510kdatabase.net/k061845/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Jun 29, 2006
Decision date	Aug 24, 2006
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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