

**K063425 DIMENSION VISTA IGE FLEX REAGENT CARTRIDGE,
PROTEIN 1 CALIBRATOR, PROTEIN 1 CONTROL MEDIUM, AND
PROTEIN 1 CONTROL HIGH**Feb 15, 2007
94 days to decisionK063425 · Product code: **DGC** · Immunology
Source: <https://www.510kdatabase.net/k063425/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ige, Antigen, Antiserum, Control (DGC)
Date received	Nov 13, 2006
Decision date	Feb 15, 2007
Days to decision	94 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

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