

**K081249 DIMENSION VISTA SYSTEM A2MAC FLEX REAGENT
 CARTRIDGE, DIMENSION VISTA SYSTEM PROTEIN 1
 CALIBRATOR, DIMENSION VISTA SYSTEM**

Jul 21, 2008
 80 days to decision

K081249 · Product code: **DEB** · Immunology
 Source: <https://www.510kdatabase.net/k081249/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alpha-2-macroglobulin, Antigen, Antiserum, Control (DEB)
Date received	May 2, 2008
Decision date	Jul 21, 2008
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k081249/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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