

**K073561 DIMENSION VISTA SYSTEM IMMUNOGLOBULIN G  
FLEX REAGENT CARTRIDGE, DIMENSION VISTA SYSTEM  
PROTEIN 1 CALIBRATOR**Feb 26, 2008  
69 days to decisionK073561 · Product code: **CFN** · Immunology  
Source: <https://www.510kdatabase.net/k073561/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Nephelometric, Immunoglobulins (g, A, M) (CFN)
Date received	Dec 19, 2007
Decision date	Feb 26, 2008
Days to decision	69 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k073561/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 19, 2026