

K072435 DIMENSION VISTA PROTEIN 3 CALIBRATOR, 3 CONTROL, 1 CONTROL L, 1 CONTROL M, 1 CONTROL HOct 17, 2007
48 days to decisionK072435 · Product code: JIX · Chemistry
Source: <https://www.510kdatabase.net/k072435/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Aug 30, 2007
Decision date	Oct 17, 2007
Days to decision	48 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 ENNIS
510(k) history	343 submissions · 343 cleared · 1978-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k072435/> 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