

**K061802 DIMENSION VISTA CARDIOPHASE HSCR P FLEX
REAGENT CARTRIDGE, PROTEIN 2 CALIBRATOR, HSCR P
CONTROL LOW, HSCR P 1 CONTROL HIGH**Sep 11, 2006
76 days to decisionK061802 · Product code: **NQD** · Chemistry
Source: <https://www.510kdatabase.net/k061802/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cardiac C-reactive Protein, Antigen, Antiserum, And Control (NQD)
Date received	Jun 27, 2006
Decision date	Sep 11, 2006
Days to decision	76 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061802/> 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