

**K053109 DIMENSION CARDIOPHASE HIGH SENSITIVITY CRP
FLEX REAGENT CARTRIDGE**Dec 23, 2005
49 days to decisionK053109 · Product code: **NQD** · Chemistry
Source: <https://www.510kdatabase.net/k053109/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cardiac C-reactive Protein, Antigen, Antiserum, And Control (NQD)
Date received	Nov 4, 2005
Decision date	Dec 23, 2005
Days to decision	49 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	ANDREA M TASKER
510(k) history	343 submissions · 343 cleared · 1978-2010

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