

K992312 K-ASSAY CRP (2), K-ASSAY CRP MULTI-CALIBRATOR A, K-ASSAY CRP MULTI-CALIBRATOR BSep 13, 1999
66 days to decisionK992312 · Product code: **DCK** · Immunology
Source: <https://www.510kdatabase.net/k992312/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C-reactive Protein, Antigen, Antiserum, And Control (DCK)
Date received	Jul 9, 1999
Decision date	Sep 13, 1999
Days to decision	66 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Kamiya Biomedical Co.
Location	Thousand Oaks, CA, US
Contact	COLIN GETTY
510(k) history	43 submissions · 43 cleared · 1991-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k992312/> 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 20, 2026