

**K991224 K-ASSAY CRP**May 14, 1999  
32 days to decisionK991224 · Product code: **DCK** · Immunology  
Source: <https://www.510kdatabase.net/k991224/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C-reactive Protein, Antigen, Antiserum, And Control (DCK)
Date received	Apr 12, 1999
Decision date	May 14, 1999
Days to decision	32 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k991224/> 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 20, 2026