

**K002558 K-ASSAY HIGH SENSITIVE CRP(2) FOR THE  
BECKMAN COULTER IMAGE**Oct 25, 2000  
72 days to decisionK002558 · Product code: **DCK** · Immunology  
Source: <https://www.510kdatabase.net/k002558/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	C-reactive Protein, Antigen, Antiserum, And Control (DCK)
Date received	Aug 14, 2000
Decision date	Oct 25, 2000
Days to decision	72 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/k002558/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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