

K011079 K-ASSAY HS-CRP CONTROLSMay 16, 2001
37 days to decisionK011079 · Product code: **DCK** · Immunology
Source: <https://www.510kdatabase.net/k011079/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	C-reactive Protein, Antigen, Antiserum, And Control (DCK)
Date received	Apr 9, 2001
Decision date	May 16, 2001
Days to decision	37 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

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