

K042241 K-ASSAY TOTAL IGE, K-ASSAY IGE CALIBRATOR SET, MODELS KAI-092/KAI-093CDec 10, 2004
113 days to decisionK042241 · Product code: **DGC** · Immunology
Source: <https://www.510kdatabase.net/k042241/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ige, Antigen, Antiserum, Control (DGC)
Date received	Aug 19, 2004
Decision date	Dec 10, 2004
Days to decision	113 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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