

K011780 K-ASSAY C1-INAJul 25, 2001
48 days to decisionK011780 · Product code: **DBA** · Immunology
Source: <https://www.510kdatabase.net/k011780/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Complement C1 Inhibitor (inactivator), Antigen, Antiserum, Control (DBA)
Date received	Jun 7, 2001
Decision date	Jul 25, 2001
Days to decision	48 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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