

K012422 K-ASSAY D-DIMER CONTROLSAug 21, 2001
22 days to decisionK012422 · Product code: **GGC** · Hematology
Source: <https://www.510kdatabase.net/k012422/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Plasma, Abnormal (GGC)
Date received	Jul 30, 2001
Decision date	Aug 21, 2001
Days to decision	22 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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