

K002948 K-ASSAY D-DIMER WITH CALIBRATOR SET AND CALIBRATOR DILUENTMay 18, 2001
239 days to decisionK002948 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k002948/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Sep 21, 2000
Decision date	May 18, 2001
Days to decision	239 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k002948/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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