

K003267 SIGMA DIAGNOSTICS AUTO D-DIMER, MODEL CRS126-AMar 15, 2001
148 days to decisionK003267 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k003267/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Oct 18, 2000
Decision date	Mar 15, 2001
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sigma Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	WILLIAM R GILBERT II
510(k) history	164 submissions · 164 cleared · 1984-2002

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