

**K013544 SIGMA DIAGNOSTICS AUTO D-DIMER CONTROL,  
LEVEL 2, MODEL A8096**Nov 15, 2001  
22 days to decisionK013544 · Product code: **DAP** · Hematology  
Source: <https://www.510kdatabase.net/k013544/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Oct 24, 2001
Decision date	Nov 15, 2001
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013544/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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