

**K080069 DIMERTEST**Feb 13, 2008  
34 days to decisionK080069 · Product code: **DAP** · Hematology  
Source: <https://www.510kdatabase.net/k080069/>**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	Jan 10, 2008
Decision date	Feb 13, 2008
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>American Diagnostica, Inc.</b>
Location	Greenwich, CT, US
Contact	LEIGH AYRES
510(k) history	10 submissions · 10 cleared · 1994-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080069/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 25, 2026