

K091916 INNOVANCE D-DIMER, MODEL OPBP09Oct 29, 2009
121 days to decisionK091916 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k091916/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Jun 30, 2009
Decision date	Oct 29, 2009
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics
Location	Newark, DE, US
Contact	KATHLEEN ANN DRAY-LYONS
510(k) history	92 submissions · 92 cleared · 2008-2025

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