

K093626 INNOVANCE D-DIMER, MODEL OPBP09Nov 29, 2010
370 days to decisionK093626 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k093626/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Nov 24, 2009
Decision date	Nov 29, 2010
Days to decision	370 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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