

K081732 INNOVANCE D-DIMER AND INNOVANCE D-DIMER CONTROLS

Oct 24, 2008
127 days to decision

K081732 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k081732/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Jun 19, 2008
Decision date	Oct 24, 2008
Days to decision	127 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k081732/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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