

K151534 HemosIL D-Dimer HSJul 6, 2015
28 days to decisionK151534 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k151534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Jun 8, 2015
Decision date	Jul 6, 2015
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Instrumentation Laboratory CO
Location	Mchenry, IL, US
Contact	NIKITA MALLADI
510(k) history	321 submissions · 320 cleared · 1976-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151534/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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