

K030328 VIDAS D-DIMER NEW (DD2) ASSAY, MODEL 30 442Sep 2, 2003
214 days to decisionK030328 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k030328/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Jan 31, 2003
Decision date	Sep 2, 2003
Days to decision	214 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	bioMerieux, Inc.
Location	Mchenry, IL, US
Contact	SANDRA PERREAND
510(k) history	251 submissions · 250 cleared · 1983-2026

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