

K040882 VIDAS D-DIMER EXCLUSION ASSAY, MODEL 30 442Jun 10, 2004
66 days to decisionK040882 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k040882/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Apr 5, 2004
Decision date	Jun 10, 2004
Days to decision	66 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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