

K041438 ADVANCED D-DIMER ASSAYAug 11, 2004
71 days to decisionK041438 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k041438/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Jun 1, 2004
Decision date	Aug 11, 2004
Days to decision	71 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	KATHLEEN DRAYLYONS
510(k) history	343 submissions · 343 cleared · 1978-2010

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