

K973819 VIDAS D-DIMER (DD) ASSAYMar 10, 1998
154 days to decisionK973819 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k973819/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP)
Date received	Oct 7, 1997
Decision date	Mar 10, 1998
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomerieux Vitek, Inc.
Location	Hazelwood, MO, US
Contact	TERRY MCGOVERN
510(k) history	49 submissions · 49 cleared · 1992-1998

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