

K050928 DADE THROMBIN REAGENTJun 29, 2005
76 days to decisionK050928 · Product code: **KQJ** · Hematology
Source: <https://www.510kdatabase.net/k050928/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Fibrinogen Determination (KQJ)
Date received	Apr 14, 2005
Decision date	Jun 29, 2005
Days to decision	76 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	KATHELEEN A DRAY-LYONS
510(k) history	343 submissions · 343 cleared · 1978-2010

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