

**K042687 ENZYGNOST F+2 (MONOCLONAL) TEST KIT**Dec 10, 2004  
72 days to decisionK042687 · Product code: **MIF** · Hematology  
Source: <https://www.510kdatabase.net/k042687/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prothrombin Fragment 1.2 (MIF)
Date received	Sep 29, 2004
Decision date	Dec 10, 2004
Days to decision	72 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dade Behring, Inc.</b>
Location	Newark,, DE, US
Contact	DONNA WOLF
510(k) history	343 submissions · 343 cleared · 1978-2010

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