

**K050513 MDA B.30**Apr 1, 2005  
31 days to decisionK050513 · Product code: **JPA** · Hematology  
Source: <https://www.510kdatabase.net/k050513/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Mar 1, 2005
Decision date	Apr 1, 2005
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>bioMerieux, Inc.</b>
Location	Mchenry, IL, US
Contact	JOCELYN JENNINGS
510(k) history	251 submissions · 250 cleared · 1983-2026

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