

K050243 IMMEDIA PROTHROMBIN TIME SYSTEMJun 6, 2005
124 days to decisionK050243 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k050243/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Feb 2, 2005
Decision date	Jun 6, 2005
Days to decision	124 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Farallon Medial, Inc.
Location	Hayward, CA, US
Contact	JAMES MCKINLEY
510(k) history	1 submissions · 1 cleared · 2005-2005

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