

K013114 BCS SYSTEMNov 9, 2001
52 days to decisionK013114 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k013114/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Sep 18, 2001
Decision date	Nov 9, 2001
Days to decision	52 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	REBECCA S AYASH
510(k) history	343 submissions · 343 cleared · 1978-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013114/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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