

K011665 BCT SYSTEMAug 9, 2001
71 days to decisionK011665 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k011665/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	May 30, 2001
Decision date	Aug 9, 2001
Days to decision	71 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/k011665/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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