

K160606 BC-5D Hematology ControlSep 1, 2016
183 days to decisionK160606 · Product code: **JPK** · Hematology
Source: <https://www.510kdatabase.net/k160606/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixture, Hematology Quality Control (JPK)
Date received	Mar 2, 2016
Decision date	Sep 1, 2016
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	R&D Systems, Inc.
Location	Mchenry, IL, US
Contact	RAVI KOMMINENI
510(k) history	79 submissions · 79 cleared · 1978-2016

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