

**K010409 CBC-SF**Mar 16, 2001  
32 days to decisionK010409 · Product code: **JPK** · Hematology  
Source: <https://www.510kdatabase.net/k010409/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixture, Hematology Quality Control (JPK)
Date received	Feb 12, 2001
Decision date	Mar 16, 2001
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>R&amp;D Systems, Inc.</b>
Location	Mchenry, IL, US
Contact	KENNETH T EDDES
510(k) history	79 submissions · 79 cleared · 1978-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010409/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026