

K970331 CBC-4K HEMATOLOGY CONTROLApr 16, 1997
78 days to decisionK970331 · Product code: **JPK** · Hematology
Source: <https://www.510kdatabase.net/k970331/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixture, Hematology Quality Control (JPK)
Date received	Jan 28, 1997
Decision date	Apr 16, 1997
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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