

K940089 CBC-COBAS 5 HEMATOLOGY CONTROL/MULTIPLEMar 22, 1994
74 days to decisionK940089 · Product code: **JPK** · Hematology
Source: <https://www.510kdatabase.net/k940089/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixture, Hematology Quality Control (JPK)
Date received	Jan 7, 1994
Decision date	Mar 22, 1994
Days to decision	74 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k940089/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026