

K944751 COULTER FLOW SETDec 8, 1994
73 days to decisionK944751 · Product code: **JPK** · Hematology
Source: <https://www.510kdatabase.net/k944751/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixture, Hematology Quality Control (JPK)
Date received	Sep 26, 1994
Decision date	Dec 8, 1994
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Coulter Corp.
Location	Hialeah, FL, US
Contact	THOMAD J ENGLISH
510(k) history	51 submissions · 51 cleared · 1989-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944751/> 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