

K081822 COULTER 6C CELL CONTROL, MODELS 628027 & A59925Jan 21, 2009
208 days to decisionK081822 · Product code: **JPK** · Hematology
Source: <https://www.510kdatabase.net/k081822/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixture, Hematology Quality Control (JPK)
Date received	Jun 27, 2008
Decision date	Jan 21, 2009
Days to decision	208 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beckman Coulter, Inc.
Location	Chaska, MN, US
Contact	LOURDES COBA
Website	https://www.beckmancoulter.com
510(k) history	270 submissions · 270 cleared · 1993-2026

Beckman Coulter, Inc. is a diagnostic device manufacturer headquartered in Chaska, US. The company specializes in clinical laboratory and immunodiagnostic systems. Beckman Coulter has received FDA 510(k) clearances from total submissions since its first clearance in 1993. The company maintains active regulatory status, with the latest clearance in 2026. Its portfolio spans chemistry devices, microbiology testing systems, hematology analyzers, and immunoassay platforms. Recent cleared devices include chemistry assays for cardiac markers, microbiology susceptibility panels,...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k081822/> 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 23, 2026