

K140911 UNICEL DXH 800 COULTER CELLULAR ANALYSIS SYSTEM/ UNICEL DXH SLIDEMAKER STAINER COULTER CELLULAR ANALYSIS SYSTEMSep 5, 2014
149 days to decisionK140911 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k140911/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Counter, Differential Cell (GKZ)
Date received	Apr 9, 2014
Decision date	Sep 5, 2014
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beckman Coulter, Inc.
Location	Chaska, MN, US
Contact	BRENT LEMBERG
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,...