

# K162414 UniCel DxH SlideMaker Stainer Coulter Cellular Analysis System

Nov 29, 2016  
92 days to decisionK162414 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k162414/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Counter, Differential Cell (GKZ)
Date received	Aug 29, 2016
Decision date	Nov 29, 2016
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Beckman Coulter, Inc.</b>
Location	Chaska, MN, US
Contact	NANCY NADLER
Website	<a href="https://www.beckmancoulter.com">https://www.beckmancoulter.com</a>
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,...