

K240252 UniCel DxH 900 Coulter Cellular Analysis SystemJul 5, 2024
157 days to decisionK240252 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k240252/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Jan 30, 2024
Decision date	Jul 5, 2024
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	UniCel DxH Slidemaker Stainer II Coulter Cellular Analysis System; UniCel DxH 690T Coulter Cellular Analysis System

APPLICANT

Company	Beckman Coulter, Inc.
Location	Chaska, MN, US
Contact	Marie Steigerwalt
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,...