FDA 510(k) Premarket Notification

K042724 MODIFICATION TO COULTER LH 500 HEMATOLOGY ANALYZER

CLEARED

Oct 29, 2004
28 days to decision

K042724 · Product code: **GKZ** · Hematology
Source: https://www.510kdatabase.net/k042724/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Counter, Differential Cell (GKZ)
Date received	Oct 1, 2004
Decision date	Oct 29, 2004
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Beckman Coulter, Inc.**
Location	Chaska, MN, US
Contact	STAN SUGRUE
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,...