FDA 510(k) Premarket Notification

# K120771 UNICEL DXH 800 COULTER CELLULAR ANALYSIS SYSTEM

**CLEARED**

Mar 22, 2013
373 days to decision

K120771 · Product code: **GKZ** · Hematology
Source: https://www.510kdatabase.net/k120771/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Counter, Differential Cell (GKZ) |
| Date received | Mar 14, 2012 |
| Decision date | Mar 22, 2013 |
| Days to decision | 373 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Beckman Coulter, Inc.** |
| Location | Chaska, MN, US |
| Contact | ERIC GRACE |
| 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,...