

**K081526 FLOWCARE TLG REAGENT**Aug 14, 2008  
73 days to decisionK081526 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k081526/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Counter, Differential Cell (GKZ)
Date received	Jun 2, 2008
Decision date	Aug 14, 2008
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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,...

---