

K240402 Cito CBC SystemFeb 3, 2025
360 days to decisionK240402 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k240402/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Counter, Differential Cell (GKZ)
Date received	Feb 9, 2024
Decision date	Feb 3, 2025
Days to decision	360 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cytochip, Inc.
Location	Irvine, CA, US
Contact	Wendian Shi
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240402/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026