

K061150 SYSMEX AUTOMATED HEMATOLOGY ANALYZER, XT-SERIESJul 6, 2006
72 days to decisionK061150 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k061150/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Apr 25, 2006
Decision date	Jul 6, 2006
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sysmex America, Inc.
Location	Mundelein, IL, US
Contact	NINA GAMPERLING
510(k) history	31 submissions · 31 cleared · 2003-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061150/> 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 June 28, 2026