

**K040073 SYSMEX AUTOMATED HEMATOLOGY ANALYZER,
XE-2100 SERIES (XE-2100, XE-2100L)**Mar 18, 2004
64 days to decisionK040073 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k040073/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Jan 14, 2004
Decision date	Mar 18, 2004
Days to decision	64 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/k040073/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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