

**K050589 RET-HE PARAMETER ON THE SYSMEX MODEL
XE-2100 AUTOMATED HEMATOLOGY ANALYZER**

May 4, 2005
57 days to decision

K050589 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k050589/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Mar 8, 2005
Decision date	May 4, 2005
Days to decision	57 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

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Device record: <https://www.510kdatabase.net/k050589/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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