

**K081610 SYSMEX MODEL XS-1000IC AUTOMATED
HEMATOLOGY ANALYZER**Aug 29, 2008
81 days to decisionK081610 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k081610/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Jun 9, 2008
Decision date	Aug 29, 2008
Days to decision	81 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/k081610/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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