

K091313 SYSMEX MODEL XT-4000IMar 30, 2010
330 days to decisionK091313 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k091313/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	May 4, 2009
Decision date	Mar 30, 2010
Days to decision	330 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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