

K160538 Sysmex XN-L Automated Hematology AnalyzerDec 22, 2016
300 days to decisionK160538 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k160538/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Feb 26, 2016
Decision date	Dec 22, 2016
Days to decision	300 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sysmex America, Inc.
Location	Mundelein, IL, US
Contact	SHARITA BROOKS
510(k) history	30 submissions · 30 cleared · 2003-2025

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