

K081890 SYSMEX XT-SERIES IG PARAMETER,SYSMEX XT-SERIES RET-HE PARAMETER

Oct 10, 2008
100 days to decision

K081890 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k081890/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Jul 2, 2008
Decision date	Oct 10, 2008
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k081890/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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