

**K031377 SYSMEX AUTOMATED COAGULATION ANALYZER
CA500 SERIES (CA-510, -520, -530, -540, -550, AND -560)**Sep 8, 2003
130 days to decisionK031377 · Product code: **GKP** · Hematology
Source: <https://www.510kdatabase.net/k031377/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Coagulation, Automated (GKP)
Date received	May 1, 2003
Decision date	Sep 8, 2003
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	RADAMES RIESGO
510(k) history	343 submissions · 343 cleared · 1978-2010

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