

**K003329 SIGMA DIANOSTICS AUTO D-DIMER CONTROL
LEVEL 2, MODEL A5217**Mar 1, 2001
128 days to decisionK003329 · Product code: **GGC** · Hematology
Source: <https://www.510kdatabase.net/k003329/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Plasma, Abnormal (GGC)
Date received	Oct 24, 2000
Decision date	Mar 1, 2001
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sigma Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	WILLIAM R GILBERT
510(k) history	164 submissions · 164 cleared · 1984-2002

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