

K000527 ACCUCLOT DRVVT SCREEN, CATALOG NO. A6094Apr 7, 2000
50 days to decisionK000527 · Product code: **GIR** · Hematology
Source: <https://www.510kdatabase.net/k000527/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Russel Viper Venom (GIR)
Date received	Feb 17, 2000
Decision date	Apr 7, 2000
Days to decision	50 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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