

K981254 SIGMA DIAGNOSTICS ACCUCLOT CONTROL IIApr 29, 1998
23 days to decisionK981254 · Product code: **GGN** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Apr 6, 1998
Decision date	Apr 29, 1998
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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