

**K981248 SIGMA DIAGNOSTICS ACCUCLOT CONTROL I**Apr 29, 1998  
23 days to decisionK981248 · Product code: **GGN** · Hematology  
Source: <https://www.510kdatabase.net/k981248/>**SUBMISSION DETAILS**

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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**

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

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