

K981255 SIGMA DIAGNOSTICS ACCUCLOT CONTROL IIIApr 29, 1998
23 days to decisionK981255 · Product code: **GGN** · Hematology
Source: <https://www.510kdatabase.net/k981255/>**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

| | |
|----------------|---|
| 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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