

**K082859 HEMOSIL ROUTINE CONTROL LEVEL 1, LEVEL 2,
LEVEL 3 UNASSAYED**Dec 19, 2008
81 days to decisionK082859 · Product code: **GGN** · Hematology
Source: <https://www.510kdatabase.net/k082859/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plasma, Coagulation Control (GGN) |
| Date received | Sep 29, 2008 |
| Decision date | Dec 19, 2008 |
| Days to decision | 81 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Instrumentation Laboratory CO |
| Location | Mchenry, IL, US |
| Contact | CAROL MARBLE |
| 510(k) history | 321 submissions · 320 cleared · 1976-2023 |

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