

K964139 SYSMEX CA-6000Feb 6, 1997
114 days to decisionK964139 · Product code: **GKP** · Hematology
Source: <https://www.510kdatabase.net/k964139/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Instrument, Coagulation, Automated (GKP) |
| Date received | Oct 15, 1996 |
| Decision date | Feb 6, 1997 |
| Days to decision | 114 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Dade Intl., Inc. |
| Location | Deerfield, IL, US |
| Contact | RADAMES RIESGO |
| 510(k) history | 30 submissions · 30 cleared · 1995-1998 |

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