

K001683 SYSMEX R-500Aug 21, 2000
81 days to decisionK001683 · Product code: **GKL** · Hematology
Source: <https://www.510kdatabase.net/k001683/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Counter, Cell, Automated (particle Counter) (GKL) |
| Date received | Jun 1, 2000 |
| Decision date | Aug 21, 2000 |
| Days to decision | 81 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Sysmex Corporation of America |
| Location | Long Grove, IL, US |
| Contact | NINA GAMPERLING |
| 510(k) history | 3 submissions · 3 cleared · 2000-2002 |

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