

K853429 COULTER COUNTER MODEL M5Oct 10, 1985
56 days to decisionK853429 · Product code: **GKL** · Hematology
Source: <https://www.510kdatabase.net/k853429/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Counter, Cell, Automated (particle Counter) (GKL) |
| Date received | Aug 15, 1985 |
| Decision date | Oct 10, 1985 |
| Days to decision | 56 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|-------------------------------------------|
| Company | Coulter Electronics, Inc. |
| Location | Mchenry, IL, US |
| Contact | RICHARDSON-JONES |
| 510(k) history | 101 submissions · 101 cleared · 1976-1994 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k853429/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026