

K251249 Tru Hematology TestJan 16, 2026
268 days to decisionK251249 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k251249/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Counter, Differential Cell (GKZ) |
| Date received | Apr 23, 2025 |
| Decision date | Jan 16, 2026 |
| Days to decision | 268 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Truvian Sciences, Inc. |
| Location | San Diego, CA, US |
| Contact | Tho Tran |
| 510(k) history | 1 submissions · 1 cleared · 2026-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251249/> 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 13, 2026