

K845019 CELL-DYN 1000 AUTOMATED HEMATOLOGY ANALYZERMar 26, 1985
89 days to decisionK845019 · Product code: **GKL** · Hematology
Source: <https://www.510kdatabase.net/k845019/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Cell, Automated (particle Counter) (GKL)
Date received	Dec 27, 1984
Decision date	Mar 26, 1985
Days to decision	89 days
Third-party review	No

APPLICANT

Company	Abbott Diagnostics
Location	Mountain View, CA, US
Contact	RUTH M BECKER
510(k) history	28 submissions · 28 cleared · 1981-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k845019/>; 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