

K803218 CELL DYN 800 HEMATOLOGY ANALYZERJun 9, 1981
173 days to decisionK803218 · Product code: **GKL** · Hematology
Source: <https://www.510kdatabase.net/k803218/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Cell, Automated (particle Counter) (GKL)
Date received	Dec 18, 1980
Decision date	Jun 9, 1981
Days to decision	173 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k803218/> 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