

**K051693 MODIFICATION TO BAYER ADVIA 2120
HEMATOLOGY ANALYZER WITH AUTOSLIDE SYSTEM**

Dec 7, 2005
167 days to decision

K051693 · Product code: **GKL** · Hematology
Source: <https://www.510kdatabase.net/k051693/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Cell, Automated (particle Counter) (GKL)
Date received	Jun 23, 2005
Decision date	Dec 7, 2005
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bayer Healthcare, LLC
Location	New York, NY, US
Contact	ANDREA HOLLE
510(k) history	46 submissions · 46 cleared · 2003-2018

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k051693/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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