

**K000611 STELLER CD61 ASSAY FOR USE ON THE IMAGN 2000  
MICROVOLUME FLUORIMETER**May 18, 2000  
85 days to decisionK000611 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k000611/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Feb 23, 2000
Decision date	May 18, 2000
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bd Biosciences</b>
Location	San Jose, CA, US
Contact	JO-ANN E FABILA
510(k) history	10 submissions · 10 cleared · 2000-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k000611/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 5, 2026