

**K080911 VARIANT NBS SICKLE CELL PROGRAM REAGENT  
KIT, VARIANT NBS NEWBORN SCREENING SYSTEM AND  
VARIANT NBS WORKSTATION WITH**May 2, 2008  
30 days to decisionK080911 · Product code: **GKA** · Hematology  
Source: <https://www.510kdatabase.net/k080911/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Abnormal Hemoglobin Quantitation (GKA)
Date received	Apr 2, 2008
Decision date	May 2, 2008
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bio-Rad Laboratories Inc., Clinical Systems Divisi</b>
Location	Hercules, CA, US
Contact	J.B BARTILSON
510(k) history	3 submissions · 3 cleared · 2006-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080911/> 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 18, 2026