

**K954048 VARIANT HEMOGLOBINOPATHY PROGRAM**Nov 20, 1995  
84 days to decisionK954048 · Product code: **GKA** · Hematology  
Source: <https://www.510kdatabase.net/k954048/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abnormal Hemoglobin Quantitation (GKA)
Date received	Aug 28, 1995
Decision date	Nov 20, 1995
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bio-Rad</b>
Location	Mchenry, IL, US
Contact	JOHN W NELSON
Website	<a href="http://www.bio-rad.com">http://www.bio-rad.com</a>
510(k) history	319 submissions · 319 cleared · 1976-2017

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k954048/> 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 May 14, 2026