

**K061047 HEMOCUE HB 301 ANALYZER, MODEL 121804 AND  
MICROCUVETTES, MODEL 111801**Jun 8, 2006  
55 days to decisionK061047 · Product code: **GKR** · Hematology  
Source: <https://www.510kdatabase.net/k061047/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Hemoglobin, Automated (GKR)
Date received	Apr 14, 2006
Decision date	Jun 8, 2006
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hemocue AB</b>
Location	Lake Forest, CA, US
Contact	ALLAN WHITE
510(k) history	6 submissions · 6 cleared · 2006-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061047/>; 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 15, 2026