

**K200909 Hemo Control (optional Add Pack Hemo Control DM)**Jun 12, 2020  
67 days to decisionK200909 · Product code: **GKR** · Hematology  
Source: <https://www.510kdatabase.net/k200909/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Hemoglobin, Automated (GKR)
Date received	Apr 6, 2020
Decision date	Jun 12, 2020
Days to decision	67 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ekf Diagnostic GmbH</b>
Location	Egale, WI, US
Contact	Andrew J. Rutter
510(k) history	5 submissions · 5 cleared · 2003-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200909/> 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