

**K163465 hemochroma PLUS System**Sep 8, 2017  
270 days to decisionK163465 · Product code: **GKR** · Hematology  
Source: <https://www.510kdatabase.net/k163465/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Hemoglobin, Automated (GKR)
Date received	Dec 12, 2016
Decision date	Sep 8, 2017
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Immunostics Inc.,</b>
Location	Ocean, NJ, US
Contact	ANTOINETTE PRUSIK
510(k) history	14 submissions · 14 cleared · 1997-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163465/> 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 25, 2026