

**K182298 hemochroma PLUS System**Nov 16, 2018  
84 days to decisionK182298 · Product code: **GKR** · Hematology  
Source: <https://www.510kdatabase.net/k182298/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Hemoglobin, Automated (GKR)
Date received	Aug 24, 2018
Decision date	Nov 16, 2018
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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