

**K160415 GEM Premier 5000 (Measured parameters: Hematocrit, Total Hemoglobin, Carboxyhemoglobin, Methemoglobin, Deoxyhemoglobin, Oxyhemoglobin, Oxygen Saturation)**Dec 14, 2016  
306 days to decisionK160415 · Product code: **GKF** · Chemistry  
Source: <https://www.510kdatabase.net/k160415/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Hematocrit, Automated (GKF)
Date received	Feb 12, 2016
Decision date	Dec 14, 2016
Days to decision	306 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Instrumentation Laboratory CO</b>
Location	Mchenry, IL, US
Contact	Carol Marble
510(k) history	321 submissions · 320 cleared · 1976-2023

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