

K163215 AnemoCheckSep 13, 2017
301 days to decisionK163215 · Product code: **KHG** · Hematology
Source: <https://www.510kdatabase.net/k163215/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Whole Blood Hemoglobin Determination (KHG)
Date received	Nov 16, 2016
Decision date	Sep 13, 2017
Days to decision	301 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sanguina, LLC
Location	Atlanta, GA, US
Contact	ERIKA TYBURSKI
510(k) history	1 submissions · 1 cleared · 2017-2017

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