

**K100103 SPECIALTY ASSAYED CONTROL-2**Dec 15, 2010  
336 days to decisionK100103 · Product code: **GGC** · Hematology  
Source: <https://www.510kdatabase.net/k100103/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Plasma, Abnormal (GGC)
Date received	Jan 13, 2010
Decision date	Dec 15, 2010
Days to decision	336 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Helena Laboratories</b>
Location	Mchenry, IL, US
Contact	PATRICIA FRANKS
510(k) history	280 submissions · 280 cleared · 1978-2013

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100103/> 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 14, 2026