

**K251440 CRYOcheck Chromogenic Factor VIII**Aug 25, 2025  
108 days to decisionK251440 · Product code: **GGP** · Hematology  
Source: <https://www.510kdatabase.net/k251440/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	May 9, 2025
Decision date	Aug 25, 2025
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Precision Biologic, Inc.</b>
Location	Dartmouth, N.S., CA
Contact	Karen Black
510(k) history	7 submissions · 7 cleared · 2004-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251440/> 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