

K214002 CRYOcheck Chromogenic Factor IXDec 23, 2022
367 days to decisionK214002 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k214002/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Dec 21, 2021
Decision date	Dec 23, 2022
Days to decision	367 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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