

K193204 Cryocheck Chromogenic Factor VIIIJul 17, 2020
240 days to decisionK193204 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k193204/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Nov 20, 2019
Decision date	Jul 17, 2020
Days to decision	240 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Precision Biologic
Location	Dartmouth, N.S., CA
Contact	Karen Black
510(k) history	10 submissions · 10 cleared · 1999-2020

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