

K183440 CRYOcheck FVIII Inhibitor KitMar 12, 2019
90 days to decisionK183440 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k183440/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Dec 12, 2018
Decision date	Mar 12, 2019
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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