

K222831 CRYOcheck Factor VIII Deficient Plasma with VWFSep 13, 2023
359 days to decisionK222831 · Product code: **GJT** · Hematology
Source: <https://www.510kdatabase.net/k222831/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Sep 19, 2022
Decision date	Sep 13, 2023
Days to decision	359 days
Third-party review	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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