

**K990296 CRYOCHECK PREKALLIKREIN DEFICIENT PLASMA,
MODEL FDPK10/10 (10 X 1.0 ML), FDPK10/25 (25 X 1.0ML)**Mar 18, 1999
49 days to decisionK990296 · Product code: **GJT** · Hematology
Source: <https://www.510kdatabase.net/k990296/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Jan 28, 1999
Decision date	Mar 18, 1999
Days to decision	49 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k990296/> Data sourced from FDA 510(k) public records (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. - Generated June 15, 2026