

**K990814 CRYO CHECK FACTOR 2 DEFICIENT PLASMA,
MODELS FDPO2-10, FDP02-15**

Jun 7, 1999
88 days to decision

K990814 · Product code: **GJT** · Hematology
Source: <https://www.510kdatabase.net/k990814/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Mar 11, 1999
Decision date	Jun 7, 1999
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k990814/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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