

K971226 CRYO CHECK FACTOR IX DEFICIENT PLASMAJul 18, 1997
107 days to decisionK971226 · Product code: **GJT** · Hematology
Source: <https://www.510kdatabase.net/k971226/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Apr 2, 1997
Decision date	Jul 18, 1997
Days to decision	107 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Precision Biologicals, Inc.
Location	Dartmouth, CA
Contact	STEPHEN L DUFF
510(k) history	20 submissions · 20 cleared · 1989-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971226/> 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 28, 2026