

**K971227 CRYO CHECK FACTOR X DEFICIENT PLASMA**Jul 18, 1997  
107 days to decisionK971227 · Product code: **GJT** · Hematology  
Source: <https://www.510kdatabase.net/k971227/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971227/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026