

**K981173 CRYO CHECK FACTOR XI DEFICIENT PLASMA,  
MODEL FDP11-10 (1.0ML) AND FDP11-15 (1.5ML)**Jan 13, 1999  
287 days to decisionK981173 · Product code: **GJT** · Hematology  
Source: <https://www.510kdatabase.net/k981173/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Apr 1, 1998
Decision date	Jan 13, 1999
Days to decision	287 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Precision Biologicals, Inc.</b>
Location	Dartmouth, CA
Contact	SANDY MORRISON
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/k981173/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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