

**K933441 STAGO FACTOR X-DEFICIENT PLASMA**Oct 27, 1993  
105 days to decisionK933441 · Product code: **GJT** · Hematology  
Source: <https://www.510kdatabase.net/k933441/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Jul 14, 1993
Decision date	Oct 27, 1993
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>American Bioproducts Co.</b>
Location	Parsippany, NJ, US
Contact	ANDREW LOC B LE
510(k) history	79 submissions · 75 cleared · 1985-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k933441/> 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