

K933444 STAGO FACTOR XI-DEFICIENT PLASMAOct 27, 1993
105 days to decisionK933444 · Product code: **GJT** · Hematology
Source: <https://www.510kdatabase.net/k933444/>**SUBMISSION DETAILS**

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

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

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