

K933440 STAGO FACTOR VII-DEFICIENT PLASMAOct 27, 1993
105 days to decisionK933440 · Product code: **GJT** · Hematology
Source: <https://www.510kdatabase.net/k933440/>**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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k933440/> 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