

**K935057 FACTOR VIII DEFICIENT PLASMA**Mar 15, 1994  
145 days to decisionK935057 · Product code: **GJT** · Hematology  
Source: <https://www.510kdatabase.net/k935057/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Oct 21, 1993
Decision date	Mar 15, 1994
Days to decision	145 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sigma Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	DANIEL E LAWSON
510(k) history	164 submissions · 164 cleared · 1984-2002

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