

**K942050 HEMOLAB COFAC IX**May 19, 1995  
386 days to decisionK942050 · Product code: **GJT** · Hematology  
Source: <https://www.510kdatabase.net/k942050/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Apr 28, 1994
Decision date	May 19, 1995
Days to decision	386 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biomerieux Vitek, Inc.</b>
Location	Hazelwood, MO, US
Contact	CHERYL WINTERS-HEARD
510(k) history	49 submissions · 49 cleared · 1992-1998

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