

**K931992 HEMOLAB**Dec 22, 1994  
608 days to decisionK931992 · Product code: **GKP** · Hematology  
Source: <https://www.510kdatabase.net/k931992/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Coagulation, Automated (GKP)
Date received	Apr 23, 1993
Decision date	Dec 22, 1994
Days to decision	608 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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