

K935850 BIOMERIEUX HEMOLAB COFAC VIIJan 17, 1995
405 days to decisionK935850 · Product code: **GJT** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Dec 8, 1993
Decision date	Jan 17, 1995
Days to decision	405 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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