

K925493 BIOMERIEUX HEMOLAB THROMBICALCI-TESTApr 21, 1994
535 days to decisionK925493 · Product code: **GJA** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Thrombin Time (GJA)
Date received	Nov 2, 1992
Decision date	Apr 21, 1994
Days to decision	535 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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