

K921989 FDP - SLIDEX DIRECTNov 3, 1993
554 days to decisionK921989 · Product code: **GHH** · Hematology
Source: <https://www.510kdatabase.net/k921989/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fibrin Split Products (GHH)
Date received	Apr 28, 1992
Decision date	Nov 3, 1993
Days to decision	554 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomerieux Vitek, Inc.
Location	Hazelwood, MO, US
Contact	DAVID K BROADWAY
510(k) history	49 submissions · 49 cleared · 1992-1998

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