

K920001 HEMOLAB SILIMAT REAGENTSep 25, 1992
267 days to decisionK920001 · Product code: **GFI** · Hematology
Source: <https://www.510kdatabase.net/k920001/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Osteotome, Manual (GFI)
Date received	Jan 2, 1992
Decision date	Sep 25, 1992
Days to decision	267 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k920001/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026