

K934210 HEMOLAB PROTEIN C CHROMOGENIC ASSAYDec 22, 1994
479 days to decisionK934210 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k934210/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Aug 30, 1993
Decision date	Dec 22, 1994
Days to decision	479 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k934210/> 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