

K843215 FACTOR IX DEFICIENT PLASMA, B9D -Nov 19, 1984
96 days to decisionK843215 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k843215/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Aug 15, 1984
Decision date	Nov 19, 1984
Days to decision	96 days
Third-party review	No

APPLICANT

Company	Sigma Chemical Co.
Location	Mchenry, IL, US
Contact	DEO BRESSLER
Website	https://www.sigmaaldrich.com
510(k) history	231 submissions · 231 cleared · 1976-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k843215/> 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 May 14, 2026