

K924396 CLOTTING FACTOR-VIII-IX-XI-XII DEFICIENT PLASMAMay 21, 1993
263 days to decisionK924396 · Product code: **GJT** · Hematology
Source: <https://www.510kdatabase.net/k924396/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Aug 31, 1992
Decision date	May 21, 1993
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Behring Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	JOSEPH KICEINA
510(k) history	145 submissions · 145 cleared · 1976-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k924396/> 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