

K972288 FACTOR DEFICIENT PLASMAS - FACTOR IX (9)Jul 14, 1997
25 days to decisionK972288 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k972288/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Jun 19, 1997
Decision date	Jul 14, 1997
Days to decision	25 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Universal Reagents, Inc.
Location	Indianapolis, IN, US
Contact	JORGE MILLER
510(k) history	8 submissions · 8 cleared · 1996-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k972288/> 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