

**K973143 UNIVERSAL REAGENT FACTOR XII (TWELVE)
DEFICIENT PLASMA**Sep 25, 1997
34 days to decisionK973143 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k973143/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Aug 22, 1997
Decision date	Sep 25, 1997
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

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/k973143/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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