

K964270 UNIVERSAL REAGENT FACTOR V DEFICIENT PLASMADec 18, 1996
54 days to decisionK964270 · Product code: **GGP** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Oct 25, 1996
Decision date	Dec 18, 1996
Days to decision	54 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

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