

K964459 UNIVERSAL REAGENT FACTOR X DEFICIENT PLASMADec 18, 1996
41 days to decisionK964459 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k964459/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Nov 7, 1996
Decision date	Dec 18, 1996
Days to decision	41 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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