

**K970607 UNIVERSAL REAGENT FACTOR VII DEFICIENT
PLASMA**Apr 25, 1997
66 days to decisionK970607 · Product code: **GJT** · Hematology
Source: <https://www.510kdatabase.net/k970607/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Feb 18, 1997
Decision date	Apr 25, 1997
Days to decision	66 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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