

K972286 FACTOR DEFICIENT PLASMAS - FACTOR XI (11)Jul 14, 1997
25 days to decisionK972286 · Product code: **GJT** · Hematology
Source: <https://www.510kdatabase.net/k972286/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Jun 19, 1997
Decision date	Jul 14, 1997
Days to decision	25 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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