FDA 510(k) Premarket Notification

K970593 UNIVERSAL REAGENT FACTOR VIII DEFICIENT PLASMA

CLEARED

Apr 25, 1997
66 days to decision

K970593 · Product code: **GJT** · Hematology
Source: https://www.510kdatabase.net/k970593/

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