FDA 510(k) Premarket Notification

K962675 STA - LIATEST VWF TEST KIT

CLEARED

Oct 25, 1996
108 days to decision

K962675 · Product code: **GJT** · Hematology
Source: https://www.510kdatabase.net/k962675/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Jul 9, 1996
Decision date	Oct 25, 1996
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**American Bioproducts Co.**
Location	Parsippany, NJ, US
Contact	ANDREW LOC B. LE
510(k) history	79 submissions · 75 cleared · 1985-1998