

K971985 N-ASSAY TIA PLASMINOGEN TEST KITOct 20, 1997
144 days to decisionK971985 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k971985/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	May 29, 1997
Decision date	Oct 20, 1997
Days to decision	144 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Crestat Diagnostics, Inc.
Location	Portland, OR, US
Contact	MARY REES
510(k) history	29 submissions · 29 cleared · 1990-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971985/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026