FDA 510(k) Premarket Notification

K971985 N-ASSAY TIA PLASMINOGEN TEST KIT

CLEARED

Oct 20, 1997
144 days to decision

K971985 · 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