

**K965113 N-ASSAY TIA FIBRINOGEN TEST KIT**Apr 16, 1997  
117 days to decisionK965113 · Product code: **KQJ** · Hematology  
Source: <https://www.510kdatabase.net/k965113/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Fibrinogen Determination (KQJ)
Date received	Dec 20, 1996
Decision date	Apr 16, 1997
Days to decision	117 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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