

K970189 FIF TMMay 21, 1997
120 days to decisionK970189 · Product code: **KQJ** · Hematology
Source: <https://www.510kdatabase.net/k970189/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Fibrinogen Determination (KQJ)
Date received	Jan 21, 1997
Decision date	May 21, 1997
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Panbio, Inc.
Location	Washington, DC, US
Contact	LINDA M WILLIAMS
510(k) history	4 submissions · 4 cleared · 1991-2000

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