

K842717 COBAS-FIBROOct 17, 1984
96 days to decisionK842717 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k842717/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Jul 13, 1984
Decision date	Oct 17, 1984
Days to decision	96 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	GRIFFIN FITZGERALD
510(k) history	296 submissions · 296 cleared · 1983-1999

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