

K042919 FIBROTEK FIBNov 29, 2004
38 days to decisionK042919 · Product code: **GIS** · Hematology
Source: <https://www.510kdatabase.net/k042919/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Fibrinogen (GIS)
Date received	Oct 22, 2004
Decision date	Nov 29, 2004
Days to decision	38 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	R2 Diagnostics, Inc.
Location	South Bend, IN, US
Contact	PEGGY S CARTER
510(k) history	10 submissions · 10 cleared · 2004-2011

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