

**K913061 FIBRINOGEN DETERMINATION KIT**Oct 9, 1991  
91 days to decisionK913061 · Product code: **GIS** · Hematology  
Source: <https://www.510kdatabase.net/k913061/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Fibrinogen (GIS)
Date received	Jul 10, 1991
Decision date	Oct 9, 1991
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sigma Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	DANIEL E LAWSON
510(k) history	164 submissions · 164 cleared · 1984-2002

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