

**K951820 THROMBOPLASTIN-LI REAGENT**Oct 20, 1995  
183 days to decisionK951820 · Product code: **GJS** · Hematology  
Source: <https://www.510kdatabase.net/k951820/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Apr 20, 1995
Decision date	Oct 20, 1995
Days to decision	183 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Helena Laboratories</b>
Location	Mchenry, IL, US
Contact	PAT FRANKS
510(k) history	280 submissions · 280 cleared · 1978-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k951820/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026