

**K905857 HELENA THROMBOPLASTIN REAGENT,  
MODIFICATION**Feb 27, 1991  
75 days to decisionK905857 · Product code: **GJS** · Hematology  
Source: <https://www.510kdatabase.net/k905857/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Test, Time, Prothrombin (GJS)      |
| Date received         | Dec 14, 1990                       |
| Decision date         | Feb 27, 1991                       |
| Days to decision      | 75 days                            |
| Third-party review    | No                                 |

**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/k905857/>; 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