

**K961908 THOR HENOSTATIS ANALYZER CAT. NO. 1450, 1451**Dec 10, 1996  
208 days to decisionK961908 · Product code: **JPA** · Hematology  
Source: <https://www.510kdatabase.net/k961908/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                          |
| Submission type       | Traditional   |
| Device classification | System, Multipurpose For In Vitro Coagulation Studies (JPA) |
| Date received         | May 16, 1996  |
| Decision date         | Dec 10, 1996  |
| Days to decision      | 208 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/k961908/> 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