

**K020355 I-STAT PROTHROMBIN TIME TEST**May 14, 2002  
99 days to decisionK020355 · Product code: **GJS** · Hematology  
Source: <https://www.510kdatabase.net/k020355/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Feb 4, 2002
Decision date	May 14, 2002
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>I-Stat Corporation</b>
Location	East Windsor, NJ, US
Contact	PAUL VANDERERF
510(k) history	7 submissions · 7 cleared · 2002-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k020355/> 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