

**K891370 EDL ONE-STAGE PROTHROMBIN TIME REAGENT**Apr 21, 1989  
43 days to decisionK891370 · Product code: **GJS** · Hematology  
Source: <https://www.510kdatabase.net/k891370/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Mar 9, 1989
Decision date	Apr 21, 1989
Days to decision	43 days
Third-party review	No

**APPLICANT**

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Company	<b>Elite Diagnostic , Ltd.</b>
Location	Indianapolis, IN, US
Contact	ROY SPECK
510(k) history	5 submissions · 5 cleared · 1989-1989

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k891370/>, 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 June 29, 2026