

**K992492 PTN TEST CARTRIDGES FOR COAGUCHEK PRO SYSTEM, PTN CONTROLS FOR COAGUCHEK PRO SYSTEM**Nov 2, 1999  
99 days to decisionK992492 · Product code: **GJS** · Hematology  
Source: <https://www.510kdatabase.net/k992492/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Jul 26, 1999
Decision date	Nov 2, 1999
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diagnostics Corp.</b>
Location	Indianapolis, IN, US
Contact	LUANN OCHS
510(k) history	264 submissions · 263 cleared · 1999-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k992492/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 9, 2026