

K040296 PHOSPHOPLASTIN RLMay 24, 2004
105 days to decisionK040296 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k040296/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Feb 9, 2004
Decision date	May 24, 2004
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	R2 Diagnostics, Inc.
Location	South Bend, IN, US
Contact	PEGGY S CARTER
510(k) history	10 submissions · 10 cleared · 2004-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k040296/> Data sourced from FDA 510(k) public records (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. - Generated June 15, 2026