

K090105 LUPOTEK KCTDec 30, 2010
714 days to decisionK090105 · Product code: **GGW** · Hematology
Source: <https://www.510kdatabase.net/k090105/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Time, Partial Thromboplastin (GGW)
Date received	Jan 15, 2009
Decision date	Dec 30, 2010
Days to decision	714 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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