

**K083878 LUPOTEK CORRECTIN VL, LUPOTEK DETECTIN VL,
PLASMACON LA**Jun 25, 2010
543 days to decisionK083878 · Product code: **GIR** · Hematology
Source: <https://www.510kdatabase.net/k083878/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Russel Viper Venom (GIR)
Date received	Dec 29, 2008
Decision date	Jun 25, 2010
Days to decision	543 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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